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Prevention of risky alcohol consumption in primary health care

Do professionals care?

For reasons of consistency within this thesis, some terms have been standardised throughout the text. As a consequence the text may differ in this respect from the articles that have been published.

The research presented in this thesis was conducted at the Scientific Center for Quality of Healthcare (IQ healthcare). This center is part of the Radboud Institute for Health Sciences (RIHS), one of the approved research institutes of the Radboud University Medical Center.

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Prevention of risky alcohol consumption in primary health care

Do professionals care?

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geboren op 8 september 1988
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Contents

	page
Chapter 1	General introduction 7
Chapter 2	GPs' role security and therapeutic commitment in managing alcohol problems: a randomised controlled trial of a tailored improvement programme <i>BMC Family Practice 2014; 15: 70</i> 15
Chapter 3	Implementation strategies to enhance management of heavy alcohol consumption in primary health care: a meta-analysis <i>Addiction 2015; 110(12): 1877-900</i> 35
Chapter 4	Implementing training and support, financial reimbursement, and referral to an internet-based brief advice programme to improve the early identification of hazardous and harmful alcohol consumption in primary care (ODHIN): study protocol for a cluster randomised factorial trial <i>Implementation Science 2013; 8: 11</i> 65
Chapter 5	Professional's attitudes do not influence screening and brief interventions rates for hazardous and harmful drinkers: results from the ODHIN Study <i>Alcohol and Alcoholism 2015; 50(4): 430-437</i> 81
Chapter 6	Improving the delivery of brief interventions for heavy drinking in primary health care: outcome results of the ODHIN five country cluster randomised factorial trial <i>In revision</i> 99
Chapter 7	Impact of primary healthcare providers' demographics, initial role security and therapeutic commitment and working conditions on implementing brief interventions in managing risky alcohol consumption: a cluster randomised factorial trial <i>In revision</i> 113
Chapter 8	Strategies in primary healthcare to implement early identification of risky alcohol consumption: why do they work or not? A qualitative evaluation of the ODHIN study <i>BMC Family Practice 2016; in press</i> 131
Chapter 9	General discussion 157
	Summary 173
	Samenvatting 179
	Dankwoord 185
	Curriculum Vitae 189
	Bibliography 191

Chapter 1

General introduction

“In some patients with complaints like yours, their condition is related to their alcohol intake. Can you tell me something about your alcohol consumption?” This is just an example of a question that primary health care providers can apply in their patient consultations, when they suspect that complaints might be caused by risky levels of alcohol consumption. This thesis is built around this topic: one question about alcohol can already result in a reduction of alcohol consumption and improve patients’ health and well-being. It would be worthwhile for providers to ask patients about alcohol habits more frequently. The overall aim of this thesis was to explore how to implement screening and brief interventions for risky alcohol consumption in the primary health care setting and to explore the impact of providers’ role perception and therapeutic commitment in managing patients with risky alcohol consumption.

Alcohol consumption: a contradictory theme

Thousands of years ago, our human ancestors were already exposed to low levels of alcohol by fermenting fruit. Humans developed genetically based tolerance and attraction for alcohol consumption as it served as a detector for locating fruiting trees.^{1,2} To date, alcohol still is part of human culture. Globally, individuals above 15 years of age drink on average 6.2 litres of pure alcohol per year, which can be translated to 13.5 grams of pure alcohol per day (in the Netherlands, 1 standard glass of alcohol contains 10 grams of pure alcohol).³ In Europe, alcohol consumption is far more common compared to other continents. To illustrate, almost 15% of the world’s population aged 15+ live in the World Health Organization (WHO) European Region, but consume a quarter of the total alcohol consumed worldwide (i.e. 23.7 grams of pure alcohol per day).³

Alcohol consumption is a contradictory and frequently discussed theme. Alcohol can bring pleasure, and may have some health benefits⁴, however the burden on health due to alcohol consumption is very high.⁵ Globally, alcohol consumption is the fifth leading cause of ill-health and premature death, after high blood pressure, tobacco smoke (including second-hand smoke), household air pollution from solid fuels, and diets low in fruits. In the age group of 15-49 years it is the leading risk factor for the global burden of disease. In the European Union (EU) it was reported that 1 in every 7 deaths in men and 1 in every 13 deaths in women in the group aged 15-64 years was related to alcohol consumption.⁵ It contributes to more than 200 diseases, injuries and other health conditions with ICD-10 codes.³ Not only the volume, but also the pattern of drinking affects the risk of harm.⁶ The harm generally concerns injuries (intentional as well as unintentional) and risk of cardiovascular diseases (mainly ischemic heart disease and ischemic stroke). Heavy episodic drinking is an example of a harmful drinking pattern and is defined as consumption of 60 or more grams of pure alcohol (6+ standard

drinks in most countries) on at least one single occasion at least monthly.³ Another frequently used term is heavy or risky drinking, which includes those drinking at hazardous and harmful levels. Guidelines for drinking slightly differ per country, though in the Netherlands the primary health care guideline recently has been revised from 14 standard glasses (units) of alcohol per week for women and 21 units per week for men, to 1 unit a day for women and elderly (55+) and 2 units a day for men, combined with 2 days per week no alcohol consumption.⁷

The important role of primary health care

The reduction of alcohol consumption is essential for achieving global targets of reducing deaths of non-communicable diseases by 25% between 2010 and 2025.⁸ The WHO emphasises the important role of health professionals in reducing the harmful use of alcohol by “monitoring alcohol consumption in their patients and providing brief interventions, counselling and pharmacotherapy, as appropriate, in all cases of identified hazardous drinking or alcohol use disorder”.³ Primary health care is a setting with enormous potential for improving health outcomes through early intervention in the chronic disease process.⁹ There is a wealth of evidence for the effectiveness of alcohol screening and brief interventions (SBI) in adults who are not seeking treatment for alcohol-related problems in primary health care.¹⁰⁻¹³ The number needed to treat (NNT) in offering screening and brief interventions is eight (for every eight people treated one will change their behaviour)¹², which is relatively low compared to smoking cessation, which has a NNT of around 35 or higher.¹⁴

SBI typically comprises two key elements: first, screening a patient to help identifying those patients drinking in a potentially harmful way. The internationally used AUDIT-C instrument is commonly used and reports consistently good performance¹⁵, and is with three questions the shortened version of the full AUDIT which comprises ten questions.¹⁶ Second, SBI comprises delivery of brief intervention to screen positives, which is designed to promote awareness of the negative effects of alcohol consumption and to motivate change.¹⁷ Although the actual content of a brief intervention varies, they typically contain some or all of the following elements: feedback on the person's alcohol use and any alcohol-related harm; clarification as to what constitutes low risk alcohol consumption; information on the harms associated with risky alcohol use; benefits of reducing intake; motivational enhancement; analysis of high risk situations for drinking and coping strategies; and the development of a personal plan to reduce consumption.¹¹ Brief interventions to reduce heavy drinking are cost-effective and widely available in primary health care. Interestingly, more intensive interventions are not more effective than less intensive interventions.¹¹

Barriers for screening and brief interventions in primary health care

Despite the evidence for cost-effectiveness of SBI¹⁸, it is hardly implemented in primary health care with less than 10% of heavy drinkers identified and offered a brief intervention.¹⁹ In the Netherlands alcohol is the least discussed lifestyle theme compared to smoking, physical activity and dietary habits. When it actually is discussed, duration is shorter compared to the other general lifestyle themes.²⁰ The barriers internationally reported for not offering screening and/or brief interventions, could roughly be categorised into three categories.²¹ First, evidence suggests there is substantial lack of knowledge among general practitioners (GPs). Additionally, they reported low levels of role security and therapeutic commitment of providers against working with patients that consume alcohol in a harmful way. GPs that reported higher levels of education for alcohol problems and that reported higher levels of role security in managing patients, managed more patients.²² Nurses, who are regarded as specialists in health promotion, selectively provide interventions which are not always optimally focused on the population that can actually benefit from brief interventions.²³ Second, lack of resources such as financial incentives and support services were frequently reported as barriers for applying SBI.^{21,24,25} Finally, heavy work load and work pressure were reported as barriers for increasing attention for alcohol use.²⁵

This thesis aims to provide knowledge about how to overcome SBI barriers in successful implementation strategies for getting SBI embedded in routine primary health care. The focus is on explaining why some strategies work, and some strategies do not work or work suboptimal. Getting more knowledge about the importance of professional's role security and therapeutic commitment in working with harmful drinkers, is a way to provide more insight in the process of change. With more knowledge about the process of successful implementation determinants, one will be able to optimise implementation strategies for SBI in primary health care.

Exploring effective implementation strategies

The sense of urgency to improve implementation of SBI in primary health care has resulted in various projects with the aim to implement SBI in routine primary health care. PHEPA²⁶, BISTAIRS²⁷ and AMPHORA²⁸, are examples of international large-scale projects with the aim to improve SBI in a range of healthcare settings. The international ODHIN project, started in 2011 and ended in 2014, aimed to strengthen the science basis to help bridging the know-do gap between scientific findings and everyday clinical practice for identification and brief intervention programs for hazardous and harmful alcohol consumption in primary health care settings.²⁹ The content of this Ph.D. thesis is largely based on the studies conducted within the ODHIN project, which focused specifically on the implementation of screening and brief intervention in primary health care and the role of providers' role security and therapeutic commitment in this process.

Aim of the thesis

This thesis focused on various interventions for implementing SBI in the primary health care setting. Additionally, the aim of this thesis included the impact of providers' role security and therapeutic commitment in managing patients with harmful alcohol consumption. We applied a variety of research methods, each of them described in separate sections.

Outline of the thesis

Chapter 2 evaluates the effects of a tailored multi-faceted improvement implementation program on GPs' role security and therapeutic commitment and, in addition, which professional related factors influenced the impact of the implementation program in a randomised controlled trial. Results were derived from the GPA trial that included 82 Dutch general practices.

Chapter 3 describes the results of a meta-analysis. This chapter describes elements from implementation strategies that have impact on decreasing heavy alcohol consumption in primary health care.

Chapter 4 presents a study protocol in which the methods of the ODHIN five country cluster randomised factorial trial were described. The aim of the trial was to evaluate the impact of training and support, financial reimbursement, and referral to an internet-based method of delivering advice (e-BI), singly or in combination, on primary health care providers' intervention rates for risky drinkers. Process measures included health professionals' role security and therapeutic commitment of the participating providers.

Chapter 5 describes the relation between existing levels of alcohol screening and brief intervention rates, and role security and therapeutic commitment by the participating primary health care professionals. Results were derived from baseline measurements of the trial as described in chapter 4.

Results of the ODHIN trial as presented in the study protocol from chapter 4 on primary health care providers' intervention rates for risky drinkers, were described in **Chapter 6**. A total of 120 primary health care units throughout five European countries were randomised to either receiving three different strategies for implementing SBI in primary health care.

Chapter 7 describes the impact of primary health care providers' demographics, initial role security and therapeutic commitment and working conditions on implementing brief interventions. Results were derived from the ODHIN cluster randomised factorial trial.

Chapter 8 presents the results of a qualitative study to explain the main findings of the cluster randomised factorial trial as a process-evaluation. The realist evaluation perspective was applied to explore why, how and in what circumstances the tested implementation strategies from the cluster randomised factorial trial work or not.

Finally, **chapter 9** summarises and discusses the main findings of this thesis, considers its strengths and limitations, as well as the main implications for implementing screening and brief interventions for harmful alcohol consumption in (primary) health care. The thesis concludes with a summary in English and in Dutch.

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Chapter 2

*GPs' role security and therapeutic commitment in
managing alcohol problems: a randomised controlled
trial of a tailored improvement programme*

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Abstract

Background: General practitioners with more positive role security and therapeutic commitment towards patients with hazardous or harmful alcohol consumption are more involved and manage more alcohol-related problems than others. In this study we evaluated the effects of our tailored multi-faceted improvement implementation programme on GPs' role security and therapeutic commitment and, in addition, which professional related factors influenced the impact of the implementation programme.

Methods: In a cluster randomised controlled trial, 124 GPs from 82 Dutch general practices were randomised to either the intervention or control group. The tailored, multi-faceted programme included combined physician, organisation, and patient directed alcohol-specific implementation strategies to increase role security and therapeutic commitment in GPs. The control group was mailed the national guideline and patients received feedback letters. Questionnaires were completed before and 12 months after start of the programme. We performed linear multilevel regression analysis to evaluate effects of the implementation programme.

Results: Participating GPs were predominantly male (63%) and had received very low levels of alcohol related education before start of the study (0.4 h). The programme increased therapeutic commitment ($p = 0.005$; 95%-CI 0.13 - 0.73) but not role security ($p = 0.58$; 95%-CI -0.31 - 0.54). How important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline, contributed to the effect of the programme on therapeutic commitment.

Conclusions: A tailored, multi-faceted programme aimed at improving GP management of patients with hazardous and harmful alcohol consumption improved GPs' therapeutic commitment towards patients with alcohol-related problems, but failed to improve GPs' role security. How important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline, both increased the impact of the programme on therapeutic commitment. It might be worthwhile to monitor proceeding of role security and therapeutic commitment throughout the year after the implementation programme, to see whether the programme is effective on short term but faded out on the longer term.

Background

Alcohol consumption is a leading determinant for the global burden of disease.¹ From 20 grams a day, the risk of harm accumulates: risk increases for chronic diseases, cancers, related neuropsychiatric conditions, intoxication, alcoholism, accidents, injuries and violence.² Furthermore, the costs related to alcohol are €125 billion a year in Europe for health, welfare, employment and criminal justice sectors as a consequence of alcohol-attributable disease, injury and violence.³ In this study, safe to moderate consumption corresponds with 2-3 standard drinks per day for men and 1-2 for women, combined with 2 days per week without any consumption and maximum 5 and 3 drinks per occasion for men and women respectively. Hazardous and harmful alcohol consumption was assessed with the Alcohol Use Disorders Identification Test (AUDIT), an instrument developed for identification of these conditions. Scores 8-15 and 16-19 correspond with hazardous and harmful alcohol consumption, respectively.⁴

Intervening in risky patterns of drinking through screening and brief interventions at an early stage is a cost-effective way to prevent drinking problems.⁵ Primary healthcare is very suitable for such interventions because large numbers of patients with a wide range of consumption patterns can be reached.⁶⁻¹⁰ Despite the evidence, such screening and brief interventions are rarely implemented into routine clinical practice.^{11,12} Among the reasons most often cited are perceived lack of time, inadequate training, fear of antagonizing clients, the perceived incompatibility of brief alcohol intervention with primary healthcare, and the belief that those who are dependent on alcohol do not respond to interventions.^{11,13-15}

The engagement of general practitioners (GPs) in the prevention of alcohol problems can be explained by behavioural theories. The ASE model, which is based on the Theory of Planned Behaviour¹⁶, is one of the models that often has been used to explain behaviours.^{17,18} The model assumes that behaviour can be predicted by the behavioural intention, which is determined by the individual's Attitude, Social support and self-Efficacy. Moving from professional's intentions to real actions depends on the person's abilities and environmental barriers.

There is considerable evidence that GPs with more positive role security and therapeutic commitment towards patients with hazardous or harmful alcohol consumption are more involved and manage more alcohol-related problems than others.¹⁹⁻²¹ Anderson et al.²⁰ have shown that GPs who received more education on alcohol; perceived that they were working in a supportive environment, expressed higher role security in working with alcohol problems, and reported greater therapeutic commitment to working with alcohol problems, were more likely to manage clients with alcohol-related problems. A negative attitude appeared to be an implementation barrier in behavioural change. Their training and support did not improve role security nor therapeutic commitment. The authors recommended that emotional responses of the GPs should be monitored more carefully in future quality improvement

programmes, for example through on-site agents or facilitators.²⁰ Correspondingly, Funk et al. suggested to increase success rates of dissemination of brief interventions that support strategies that address therapeutic commitment, role security and beliefs more profoundly should be explored.²²

To further explore in what way GPs' role security and therapeutic commitment could be positively influenced, we developed a tailored implementation programme, targeted at role security and therapeutic commitment and incorporated the above recommendations. This multifaceted alcohol specific implementation strategy included professional, organisational and patient-directed strategies. We aimed to study 1) the effect of a multi-faceted implementation strategy on the providers' role security and therapeutic commitment towards alcohol-related problems; and 2) other factors which can explain the changes in role security and therapeutic commitment towards alcohol-related problems.

Methods

Design and participants

Data used in this paper were part of the GPA-project (Engaging General Practice in the prevention of patients with Alcohol problems), a cluster randomised controlled trial²³ (trial number NCT00298220). This study assessed the effect of a tailored multi-faceted improvement programme on GPs' screening of hazardous and harmful alcohol consumption and brief intervention rates as well as on role security and therapeutic commitment. Effects of this trial on screening and brief intervention rates and on patient reported alcohol consumption were described elsewhere.^{4,23}

Data were collected with measurements before (T0) and 12 months after (T1) delivery of the programme. In total, 2,758 Dutch general practices were invited during three recruitment waves. Practices could only enrol if all GPs in the practice agreed to participate. To encourage enrolment, the non-participants received a reminder after two weeks, and if necessary a second reminder after again two weeks. To encourage response at post measurement, we sent reminders after two and four weeks. Dependent on allocation group and the degree of participation in the different components of the programme, GPs were offered accreditation points, i.e. Permanent Education Points. Dutch clinicians - including GPs - are obliged to achieve sufficient accreditation points in order to maintain their medical license. Accreditation points could be achieved by educational activities and are ultimately granted by a department of the Royal Dutch Medical Association (KNMG).

The trial was approved by the Research Ethics Committee CMO of the region Arnhem-Nijmegen (letter dated 2 January 2006; SE/CMO 0003). The committee concluded in their letter that in compliance with the law on medical-scientific research (WMO), the GPA trial did not need approval. We asked for written informed consent, which was provided by all participants.

Randomisation and allocation

The enrolled practices were randomised by a computerised scheme (block randomisation) to an equal-sized intervention group and control group. Randomisation was done at two moments: after the first two recruitment waves and again after the third wave. The improvement programme was offered to the general practices during October 2006 to June 2007 (intervention period). After randomisation, the practices were divided into clusters for logistic reasons, dependent on their location in the Netherlands. Clusters one through six (all from recruitment wave one or two) started the programme in October 2006 and their last possible activity was in May 2007. Clusters seven and eight (wave three) started the programme in December 2006 and also ended in May 2007. The programme was offered in eight clusters, but the content of those eight clusters was consistent. The research team organised and delivered the intervention, which made it impossible to blind the research team for practice allocation.

Implementation programme

The intervention combined physician, organisation, and patient directed alcohol-specific implementation strategies. The emphasis was on educational training sessions and support visits by a trained facilitator, which were tailored to the providers' needs and attitudes (see Table 1). The tailoring during training and during support visits was especially focused on the baseline role security and therapeutic commitment of the providers. During the first training session the baseline role security and therapeutic commitment of the providers were discussed and presumptions towards hazardous and harmful levels of alcohol consumption were addressed. Furthermore, the theoretical basics were discussed, i.e. definitions over risky alcohol consumption, epidemiology, risk of alcohol consumption, risk groups, symptoms and possible (brief) interventions. The second and third sessions focused on bringing theory into practice to overcome the barriers that hinder GPs. After a short summary of the theory about how to approach alcohol problems, the participants were able to revert to unfinished matters from the first session of support visit (if attended) or to bring in cases from their daily practice. Next, the GPs practiced motivational interviewing in role plays, a useful method in the treatment of lifestyle problems and disease. The focus in the role plays depended on the role security, therapeutic commitment and experiences of the participating GPs. During support visits barriers of the practice organisation as a whole, were addressed. First, remaining questions after the educational training sessions were discussed. Next, implementation barriers in daily practice were addressed. Besides practical tips to tackle structural, logistical and communication issues, the facilitator focused on the role security and therapeutic commitment of the practice team and discussed individual barriers to act upon alcohol problems. Staff delivering training and support

strategies were trained using a detailed standardised protocol and written scripts and guidance.

So, the intervention group received a partly standardised intervention, where education and support were tailored to individual needs. These parts of the programme were tailored as we hypothesised that GPs are more likely to increase their role security and therapeutic commitment in a tailored programme compared to a standardised programme which may not optimally match their baseline rates. Variability within the programme is inherent to tailoring and is expected to result in maximal improvement in role security and therapeutic commitment. Furthermore, physicians as well as patients received feedback from patient AUDIT scores²³, through personal feedback. For a detailed outline of the programme, see Table 1.

Table 1. Outline of the intervention programme

<i>GP directed interventions</i>	
1	Distribution of the guideline on problematic alcohol consumption issued by the Dutch college of GPs
2	A reminder-card to display on desk of the GP. This card featured the signs, symptoms and characteristics which should trigger a physician to ask about alcohol consumption. At the back site the Five Shot Test was listed, a five-item questionnaire to designed to estimate the amount of alcohol consumption of a patient, which is recommended in general practice because of its practical advantages and diagnostic properties.
3	Educational training session tailored to professionals' attitudes. The entire general practice team (including practice assistants and nurses) was invited to participate in the small-scale training sessions (maximum around ten participants). Minimally one and maximally three sessions could be attended, tailored to the wishes, needs, and attitude of the teams. These sessions were offered to the practice teams in the early evening hours together with a light dinner (soup, bread, fruits). The duration of the sessions was between two and three hours. The basic content of the educational trainings was based on the guidelines of the Dutch college of GPs and on recent international guidelines. More in detail, the content was tailored to the attitudes of the GPs. In order to identify the attitudes towards and experiences with alcohol problems the Short Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ) was used. During the first training session the outcomes of the SAAPPQ were discussed and presumptions towards hazardous and harmful levels of alcohol consumption were addressed. Furthermore, the theoretical basics were discussed. And finally, the local addiction services were invited to participate in this session (see ' <i>Organisation/practice directed interventions</i> '). The second and third sessions focussed on bringing theory into practice to overcome the barriers that hinder GPs. After a short summary of the theory about how to approach alcohol problems, the participants were able to revert to unfinished matters from the first session of support visit (if attended) or to bring in cases from their daily practice. Next, the GPs practiced motivational interviewing in role plays, a useful method in the treatment of lifestyle problems and disease. The casuistry in the role plays depended on the attitude and experiences of the participating GPs.
<i>Organisation/ practice directed interventions</i>	
4	Feedback identifying the number of patients who are at risk because of their alcohol consumption. From the AUDIT patient questionnaires, distributed by the practice teams, the amount of alcohol consumption for each responding patient was calculated. The patients were divided into 4 categories: I. Safe to moderate drinker; II. Hazardous drinker; III. Harmful drinker; IV. Possibly dependant drinker. For each practice the proportion of patients in every category were calculated. The practices received this anonymous information together with the total number of returned patient questionnaires.

5	Facilitation of the cooperation with local addiction services for support and referral. The local addiction services were invited to join in the first educational training session. The goals were that the practice teams took cognizance of the experiences of the addiction services, that the GPs knew more precisely when to refer and what subsequently happened to their patients and to come to agreements about communication, accessibility, and cooperation.
6	Outreach visitor support by a trained facilitator tailored to needs of practice. Again, the entire practice team was invited and participation was tailored to the wishes and needs of the teams. Minimally one and maximally three support visits were offered. The visits took place during daytime and lasted around one hour. The content of the support visits was tailored to the barriers of the practice organisation as a whole. First, remaining questions after the educational training sessions were dealt with. Implementation barriers in daily practice were addressed next. Besides practical tips to tackle structural, logistical and communicative issues the facilitator focussed on the attitudes and beliefs of the practice team and discussed individual barriers to act upon alcohol problems.
<i>Patient directed interventions</i>	
7	Patient information letters about alcohol issued by the Dutch college of GPs and leaflets and self-help booklets issued by the NIGZ. These patient materials were offered to the general practices in order to be distributed by the GPs.
8	Poster in the waiting room. This gaudy poster drew the attention to alcohol with the advice to contact the GP or look at the websites of the NIGZ (National Institute for Health Promotion and Disease Prevention) or Trimbos (National institute of knowledge about mental healthcare, addiction services and societal care) for further information.
9	Personal feedback based on their alcohol consumption. The patients received a letter which cited the category to which they belonged and the corresponding advices. The advices were to turn to their GP or to look at the websites of the NIGZ or Trimbos. For patients in category I this was not necessary and for patients in category IV we added the advice to inquire at the local addiction service

The control group was mailed the national guideline²⁴ (which was publicly available) and patient information letters on problematic alcohol consumption developed by the Dutch College of General Practitioners in order to distribute to patients by GPs when appropriate. The GPs did not receive further support or training. For ethical reasons, the patients also had to receive the personalized feedback on alcohol consumption in May 2007, which can be assessed as a minimal intervention, but took place after the physician programme ended.

Outcome measurements

This paper describes outcomes on the GPs' role security and therapeutic commitment. These were measured before and after the implementation programme, using the 10-item Shortened Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ). The SAAPPQ has been developed in England as a quick yet meaningful measure of GPs' attitudes to working with drinkers, either as a way of measuring change over time or when planning intervention strategies.²⁵ We translated the questionnaire into Dutch, and independently back-translated it into English to check accuracy of the initial translation, both literally and idiomatically.

The role security domain within the SAAPPQ includes 2 sub-domains: role adequacy, and role legitimacy (e.g. "I feel I can appropriately advise my patients about drinking

and its effects”; “I feel I have the right to ask patients questions about their drinking when necessary”). Therapeutic commitment involves motivation, task specific self-esteem, and work satisfaction. Within the scales of role security and therapeutic commitment (ratings on a 7-point Likert scale ranging from ‘strongly agree’ to ‘strongly disagree’) means were calculated. For the questions of the SAAPPQ with additional scoring key, see Additional file 1.

Additionally, we added questions to the pre-measurement questionnaire about the providers’ characteristics, such as age, gender, practice size (number of patients per physicians), full-time equivalent (FTE), and the degree of urbanisation of the practice. Moreover, we asked how important GPs thought it was to improve their identification of patients with alcohol-related problems (both before and after intervention), how important GPs thought it was to improve care for patients with alcohol-related problems (both before and after intervention), degree of alcohol-related education, the GPs’ reported proportion of patients asked about their alcohol consumption (both before and after intervention), proportion of patients counselled by the GP for alcohol related problems (both before and after intervention), degree of participation in the intervention programme, and correct or incorrect estimating the maximum number of drinks by the guideline (both before and after intervention). The post measurement questionnaire was similar although questions about provider characteristics such as practice type, patient load, etc. were excluded.

Sample size

A power calculation was carried out to estimate the number of practices to be included to detect the effect of the implementation programme in changing providers’ advice giving behaviour and is described elsewhere.²³ We intended to recruit 80 general practices.

Statistical analysis

Practice was the unit of allocation. Because of the hierarchical structure (GPs nested within practices), we performed a linear multilevel (mixed model) analysis. In this analyses we take account of the variability associated with each level of nesting. In a mixed model both fixed and random effects can be analysed. We performed a model with a random intercept for practices and all other variables fixed, as these were used to correct the effect. Subsequently, we investigated the effect of the implementation programme on domains of role security and therapeutic commitment as a continuous outcome variable. Multilevel linear regression analysis with the follow up score as outcome and baseline score as covariate was used to evaluate the effect of the implementation programme. Descriptive statistics were used to describe the characteristics of participating GPs at baseline.

During the second wave, the SAAPPQ had a systematic flaw. The last SAAPPQ-question "In general, I like drinkers" was systematically missing and caused a missing value, concerning 67 GPs. All participants that had missings in their measurements, were assigned a value based on multiple imputation procedure. All of the potential determinants of effects were used for calculating the imputation. It is suggested that multiple imputation yields less bias and less variability than the often used last observation carried forward method.²⁶ Before the multiple imputation, we checked all the variables in the absence of a significant difference between the group with the systematic missing (i.e. second wave), to the group without the significant missing (i.e. first and third wave). After multiple imputation, the sample did not significantly differ from the former sample without multiple imputation. To maintain the power, we decided to proceed with the multiple imputation sample.

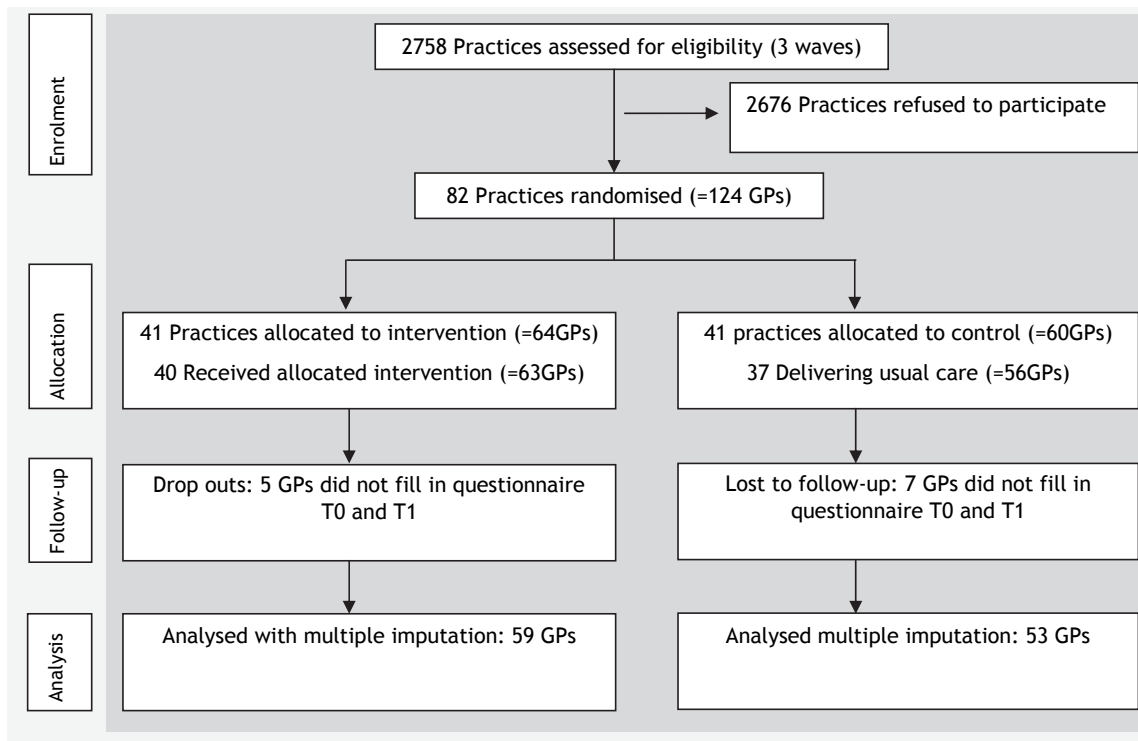
We added the following factors from baseline separately to explain the changes in the effects on role security and therapeutic commitment towards alcohol-related problems, as we thought they might determine the effect of the implementation programme: age, gender, full time equivalent, size of patient population, working area, practice setting (solo, duo, group, etc.), how important GPs thought it was to improve their identification of patients with alcohol-related problems (both before and after intervention), how important GPs thought it was to improve care for patients with alcohol-related problems (both before and after intervention), degree of alcohol-related education, the GPs' reported proportion of patients asked about their alcohol consumption (both before and after intervention), proportion of patients counselled by the GP for alcohol-related problems (both before and after intervention), degree of participation in the intervention programme, and correct or incorrect estimating the maximum number of drinks by the guideline (both before and after intervention). Furthermore, we added interaction terms in order to identify interactive effect of the programme (effect modification). We considered a p-value < 0.05 statistically significant. Descriptive analyses was conducted using SPSS version 20.0 (IBM PASW statistics 20) and multilevel regression analyses was conducted using SAS V9.2 (SAS Institute Inc., Cary, NC, USA).

Results

Study population

Figure 1 outlines the study design and the flow of participating practices and GPs. The participating 82 practices with 124 GPs were randomised. After randomisation but before pre measurement, five practices withdrew: one in the intervention group and four in the control group (no data available). This resulted in 40 practices (63 GPs) receiving allocated intervention and 37 practices (56 GPs) in the control group.

Figure 1. Participant flow



With regard to the baseline and follow-up measurement, 112 GPs delivered sufficient information to be included in the analysis: 59 in the intervention group and 53 in the control group.

Descriptive demographics of the GPs are detailed in Table 2. GPs of the intervention and control group only significantly differed in age: GPs of the intervention group turned out to be on average 4 years younger than their colleagues in the control group, but in both groups the majority of GPs was middle-aged (45-50 years).

Table 2 also includes baseline role security and therapeutic commitment. The role security and therapeutic commitment levels of the control group are not different compared to the intervention group. For results on the 10 single SAAPPQ questions from which role security and therapeutic commitment in Table 2 were calculated, see Additional file 2.

Table 2. Baseline characteristics of participating and non-participating GPs

<i>Characteristic</i>	<i>Intervention (N=59)</i>	<i>Control (N=53)</i>	<i>Non-participants (N=761)</i>
Male gender	39 (66%)	31 (58.5%)	478 (65.4%) [#]
Mean age at start of study (SD)	45 (6.9) [#]	49 (7.7) [#]	48.1 (8.0)
Mean FTE (SD)	0.84 (0.2)	0.97 (1.2)	0.83 (0.56)
Mean size of patient population (SD)	2158 (627)	2179 (730)	2153 (689)
<i>Working area</i>			
Rural	18 (31%)	14 (26%)	148 (20%)
Urbanised rural	23 (39%)	16 (57%)	306 (41%)
Urban	3 (5%)	10 (19%)	142 (19%)
Big city	15 (25%)	13 (25%)	145 (20%)
<i>Practice type</i>			
Solo	20 (34%)	24 (45%)	193 (26%) [#]
Duo	23 (39%)	22 (42%)	216 (29%) [#]
Group	10 (17%)	5 (9%)	213 (29%) [#]
Health Centre	6 (10%)	2 (4%)	79 (11%) [#]
Other			42 (6%) [#]
Average hours of training in alcohol problems before start of study (SD)	0.51 (1.1)	0.36 (0.97)	n.m.
<i>Role security[‡]: total (SD)*</i>	<i>5.0 (0.91)</i>	<i>5.1 (0.76)</i>	<i>5.2 (0.82)</i>
Role adequacy	4.4 (1.06)	4.4 (1.12)	4.6 (1.05)
Role legitimacy	5.6 (1.20)	5.7 (1.04)	5.7 (1.07)
<i>Therapeutic commitment[‡]: total (SD)*</i>	<i>3.9 (0.92)</i>	<i>3.9 (0.74)</i>	<i>3.9 (0.76)</i>
Task-specific self-esteem	3.9 (1.14)	3.7 (1.22)	4.0 (1.11)
Work satisfaction	3.3 (1.32)	3.5 (1.20)	3.6 (0.88)
Motivation	4.5 (1.06)	4.5 (1.01)	4.2 (1.10)

[#] significant difference ($p < 0.05$) compared to participating GPs; n.m. = not measured; [‡] = Role security was calculated by the average of role adequacy and role legitimacy; [‡] Therapeutic commitment was calculated by the average of task-specific self-esteem, work satisfaction and motivation; * minimum=1 and maximum=7

Non-participants

The non-participant questionnaire was returned by 761 GPs (28%). As to age, average percentage of fulltime work, caseload, and working area the participating GPs did not differ from the non-participants (see Table 2). However, the non-participating GPs worked on average in practices with more colleagues than the participating GPs, who mostly worked in solo- or duo practices ($p < 0.05$). Moreover, the non-participant population consisted of more male GPs compared to the participating population, but just with a 2% difference ($p < 0.05$). Non-participant role security and therapeutic commitment did not differ from participant baseline levels. For results on the 10 single SAAPPQ questions from which role security and therapeutic commitment were calculated, see Additional file 2.

Changes in role security and therapeutic commitment

Table 3 shows scores before and after the implementation of the programme, and the mean difference for role security and therapeutic commitment, respectively. GPs in

both intervention and control groups improved in their role security and therapeutic commitment, though the intervention group showed a higher mean score.

Table 3. Role security and therapeutic commitment before and after intervention

Role security			
<i>Attitude domains</i>	<i>Mean before (SD)</i>	<i>Mean after (SD)</i>	<i>Mean difference (SD)</i>
Intervention group	5.01 (0.91)	5.58 (0.79)	0.59 (1.11)
Control	5.08 (0.76)	5.46 (0.61)	0.31 (0.72)
Therapeutic commitment			
<i>Attitude domains</i>	<i>Mean before (SD)</i>	<i>Mean after (SD)</i>	<i>Mean difference (SD)</i>
Intervention group	3.92 (0.92)	4.58 (0.81)	0.63 (0.97)
Control	3.90 (0.74)	4.02 (0.76)	0.20 (0.64)

Corrected for baseline levels, table 4 shows the results of the multilevel analysis without and with multiple imputation for both role security and therapeutic commitment respectively. From this table we can see there were no major changes in parameters, which allows us to proceed with the multiple imputation model. The multilevel regression analysis showed that GPs in the intervention group improved in their therapeutic commitment more than 0.43 on the 7-point likert scale (95%-CI 0.13-0.73) compared to GPs in the control group. On the contrary, role security did not significantly change due to the intervention ($B = 0.11$; $p = 0.58$; 95%-CI -0.31 - 0.54).

Table 4. Role security and therapeutic commitment with and without multiple imputation

Role security				
<i>Attitude domains</i>	<i>B*</i>	<i>95%-CI</i>	<i>S.E.</i>	<i>p-value</i>
Intervention effect <u>without</u> multiple imputation	0.13	-0.18 - 0.44	0.16	0.4111
Intervention effect <u>with</u> multiple imputation	0.12	-0.31 - 0.54	0.21	0.5791
Therapeutic commitment				
<i>Attitude domains</i>	<i>B*</i>	<i>95%-CI</i>	<i>S.E.</i>	<i>p-value</i>
Intervention effect <u>without</u> multiple imputation	0.52	0.21 - 0.83	0.16	0.0017
Intervention effect <u>with</u> multiple imputation	0.43	0.13 - 0.73	0.15	0.0052

* Improvement on 7-point likert scale; 95%-CI = 95% Confidence Interval; S.E. = Standard Error

Explaining changes in role security and therapeutic commitment change

With regard to therapeutic commitment, how important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline, were identified as likely determinants of effects ($p < 0.15$). The results from Table 5 show that, corrected for these both factors, the intervention effect further increased compared to the

uncorrected intervention effect from 0.43 to 0.51 points within therapeutic commitment.

Role security did not improve due to the implementation programme. The degree of participation in the intervention programme was identified as a likely determinant of effect ($p < 0.15$), but the intervention effects remained to be non-significant. This implies that the programme did not affected role security neither in a negatively, nor positively.

Furthermore, we were not able to identify subgroups in intervention effects in terms of effect modification. Neither in the effect of the implementation programme on role security, nor on therapeutic commitment, interactive effects between potential determinants of effect could be identified.

Table 5. Determinants of intervention effect on role security and therapeutic commitment

<i>Role security</i>				
<i>Attitude domains</i>	<i>B*</i>	<i>95%-CI</i>	<i>S.E.</i>	<i>p-value</i>
Intervention effect	-0.17	-0.85 - 0.51	0.32	0.6029
Pre measurement	0.16	-0.07 - 0.38	0.11	0.1697
Participation degree	0.42	-0.11 - 0.96	0.26	0.1144
<i>Therapeutic commitment</i>				
<i>Attitude domains</i>	<i>B*</i>	<i>95%-CI</i>	<i>S.E.</i>	<i>p-value</i>
Intervention effect	0.51	0.23 - 0.80	0.14	0.0006
Pre measurement	0.60	0.32 - 0.89	0.13	0.0008
GP reported importance to improve care	0.16	0.05 - 0.28	0.06	0.0079
Proportion of patients of which the GP asked for their alcohol consumption	0.01	-0.00 - 0.02	0.01	0.0654

* Improvement on 7-point likert scale; 95%-CI = 95% Confidence Interval; S.E. = Standard Error

Discussion

The main finding of this study was that our implementation programme improved the GPs' therapeutic commitment, but despite all efforts for tailoring the intervention to the providers, it did not affect the role security. In line with this latter finding, the tailored implementation programme neither improved GPs' screening and brief intervention rates, as described elsewhere.²³

How important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline, were identified as determinants of effects on the therapeutic commitment. Nevertheless, when corrected for this, the programme remained to be effective in improving therapeutic commitment. With regard to role security, no determinants of effects were identified.

Our findings do not confirm our hypothesis that our tailored implementation programme would improve GPs' role security, despite the efforts for tailoring to providers' baseline role security. Role security is about having knowledge and skills in recognising and discussing risky alcohol consumption and role legitimacy. Looking at the

professional-oriented elements of the programme that could have influenced role security, the educational sessions and support visits were tailored to the GPs' SAAPPQ baseline scores in the sense that the outcomes of the SAAPPQ were discussed and presumptions towards hazardous and harmful levels of alcohol consumption were addressed. A possible explanation for improvement of therapeutic commitment and not for role security might be the fact that the baseline level of role security was higher than the level of therapeutic commitment, and was therefore leaving less room for improvement. Another reason for not showing a substantial improvement of role security might be that follow-up was measured only after 12 months. An initial effect on role security might have faded out by that time. Additionally, in line with our finding that the programme did not increase role security, was the fact that the study results did not show improved screening and brief intervention rates. The screening and brief intervention rates were initially improved during the implementation period, but the effects deteriorated at the end, i.e. there was no difference between the intervention group and control group.²³ This may imply that only if both role security and therapeutic commitment are improved this will have an impact on provider behaviour. Furthermore, when looking at the two sub-domains within role security, one could expect it to be easier to improve role adequacy (knowledge and skills) than role legitimacy (Additional file 1). The results indeed showed a larger improvement in role adequacy than in role legitimacy, however the difference was not sufficient to draw any firm conclusions from. It might be indicating however that more attention needs to be given to enhancing role legitimacy.

Also, similar to our findings, Anderson et al. found that training and support did not increase role security. In fact, they even found that role security and therapeutic commitment for GPs who were already role-insecure and low therapeutically committed, actually deteriorated.²⁰ We cannot confirm this finding that experience in screening and brief interventions deteriorates role security in GPs who were already insecure in their role, though we saw that how important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline, facilitated improvement of therapeutic commitment. Tailoring the intervention to the GPs' levels of role security, as we did, however, might not be sufficient to actually improve role security and subsequently screening and brief intervention behaviour. In the study of Butler et al.²⁷, it was emphasised to not just tell GPs to incorporate behaviour change counseling into their consults, but training requires more finesse in the sense that perceptions and the internally-driven processes of GPs are addressed in the training and support sessions. We think our study incorporated those elements, this may explain why we succeeded in improving therapeutic commitment.

Although the participants were only a small proportion of the total population, they largely reflected key characteristics of GPs in The Netherlands. Only on the aspect of

gender and on practice type, there was just a small difference between participating and non-participating GPs. This means that it is very likely that our results are representative for the Dutch GP population. This is interesting, since the recruitment of practices was laborious and we had to invite more practices than anticipated. Experiences from colleagues in international clinical trials learn us that it is increasingly difficult to recruit and retain GPs for clinical trials.²⁸⁻³¹

On the other side, a limitation of our study was the very limited degree of participation of the GPs in the training sessions and visits: only 59% of GPs from the intervention group met the minimal demands of enrolment. This possibly means that the acceptability of the implementation programme was suboptimal. Furthermore, we were not able to identify different effects of the implementation programme between subgroups of patients (i.e. effect modification). It is likely that the sample size was too small to detect possible effect modification. Besides, during a systematic flaw of missing a question in a part of the questionnaires, we required multiple imputation to maintain as much power as possible. However, after checking whether multiple imputation affected the results, there were no signs of any affected results.

Although we have shown that it is possible to improve GPs' therapeutic commitment, it was described in an earlier published article of this study that the implementation programme neither produced improved screening and brief intervention outcomes at the GP level²³, nor on the level of patient alcohol consumption⁴ both at one year followup. Like suggested in an earlier article of this GPA-project²³, this does not necessarily mean that the implementation programme did not work, as the transtheoretical model of (health) behaviour change suggests that it can take up to five years for new behaviour to be integrated in daily routines.³² Also, as researchers we might be too keen on having effects from implementation strategies, which results in high expectations and ambitious, high intensity implementation programmes. Probably it is more effective to take very small steps in the process of GPs incorporating prevention activities, since their practice actually is more focused on the disease model. That means that we should think about other strategies to increase role security and therapeutic commitment, find out the optimal measurement times and frequencies, and create long-term trials to monitor role security, therapeutic commitment and in the end screening and brief interventions against hazardous and harmful alcohol consumption.

Furthermore, research implementation programmes could focus on letting the implementation strategy for screening and brief interventions match as much as possible to GPs' current practice in a way of achieving 'personalised implementation', which likely is to be focused on the disease model. In addition, if it remained to be difficult to improve GPs' readiness to screen and do brief interventions, one might not use (solely) professional oriented implementation strategies aimed at GPs, but on the contrary test the effect of organisational oriented implementation strategies like

physically locating addiction care in the general practice or test the effect of substitution of preventive tasks from the GP to practice nurses. The latter might be a more low-threshold intervention. There are studies that already evaluated the effects of nurses' SBI (e.g.³³⁻³⁵), this research could be extended with evaluating task substitution from the GP to the nurse.

Lastly, it would be worthwhile to gain more insight of the GPs' attitudes over time. We had a long time between the first and last measurement, which resulted in a kind of 'black box' with regard to the attitude in due course. If it was shown that the effects faded out in time, a short booster programme may be effective in maintaining improved role security and therapeutic commitment, and maybe even maintaining improved screening and advice giving behaviour.

Conclusions

A tailored, multi-faceted programme aimed at improving GP management of patients with hazardous and harmful alcohol consumption improved GPs' therapeutic commitment towards patients with alcohol-related problems, but failed to improve GPs' role security. How important GPs thought it was to improve their care for problematic alcohol consumption, and the GPs' reported proportion of patients asked about alcohol consumption at baseline contributed to the effect of the programme on therapeutic commitment. It might be worthwhile to monitor proceeding of role security and therapeutic commitment throughout the year after the implementation programme, to see whether the programme is effective on short term but faded out.

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Additional file 1: The SAAPPQ questionnaire (English version) with scoring key

		Strongly agree	Quite strongly agree	Agree	Neither agree or disagree	Disagree	Quite strongly disagree	Strongly disagree
		1	2	3	4	5	6	7
1	I feel I know enough about causes of drinking problems to carry out my role when working with drinkers							
2	I feel I can appropriately advise my patients about drinking and its effects							
3	I feel I do not have much to be proud of when working with drinkers							
4	All in all I am inclined to feel I am a failure with drinkers							
5	I want to work with drinkers							
6	Pessimism is the most realistic attitude to take towards drinkers							
7	I feel I have the right to ask patients questions about their drinking when necessary							
8	I feel that my patients believe I have the right to ask them questions about drinking when necessary							
9	In general, it is rewarding to work with drinkers							
10	In general I like drinkers							

Scoring

Reverse scoring for items 1, 2, 5, 7, 8, 9, 10

Role adequacy: Add scores on items 1, 2
 Role legitimacy: Add scores on items 7, 8
 Motivation: Add scores on items 5, 6
 Task-specific self-esteem: Add scores on items 3, 4
 Work satisfaction: Add scores on items 9, 10

Role security: Add scores on role adequacy and role legitimacy
 Therapeutic commitment: Add scores on Motivation, Work Satisfaction and Task-specific Self-esteem

Additional file 2: Baseline role security and therapeutic commitment of participating and non-participating GPs

		Intervention (N=59)*	Control (N=53)*	Non- participants (N=761)*
1	I feel I know enough about causes of drinking problems to carry out my role when working with drinkers (mean; SD)	3.9 (1.40)	3.8 (1.3)	3.6 (1.22)
2	I feel I can appropriately advise my patients about drinking and its effects (mean; SD)	3.3 (1.18)	3.4 (1.30)	3.2 (1.15)
3	I feel I do not have much to be proud of when working with drinkers (mean; SD)	3.9 (1.31)	3.8 (1.54)	3.9 (1.32)
4	All in all I am inclined to feel I am a failure with drinkers (mean; SD)	3.8 (1.27)	3.5 (1.31)	4.0 (1.32)
5	I want to work with drinkers (mean; SD)	3.6 (1.14)	3.6 (1.34)	4.2 (1.33)
6	Pessimism is the most realistic attitude to take towards drinkers (mean; SD)	4.6 (1.39)	4.6 (1.54)	4.6 (1.47)
7	I feel I have the right to ask patients questions about their drinking when necessary (mean; SD)	2.0 (1.36)	1.9 (1.23)	1.9 (1.18)
8	I feel that my patients believe I have the right to ask them questions about drinking when necessary (mean; SD)	2.7 (1.40)	2.6 (1.30)	2.6 (1.24)
9	In general, it is rewarding to work with drinkers (mean; SD)	4.8 (1.42)	4.8 (1.31)	4.9 (1.20)
10	In general I like drinkers (mean; SD)	4.3 (1.08)	3.4 (1.14)	3.9 (1.05)

* Scores on 7-point likert scale, in which 1= Strongly agree to 7=Strongly disagree

3

Chapter 3

Implementation strategies to enhance management of heavy alcohol consumption in primary health care: a meta-analysis

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Abstract

Aims: Screening and brief interventions (SBI) delivered in primary health care (PHC) are cost-effective in decreasing alcohol consumption; however, they are underused. This study aims to identify implementation strategies that focus on SBI uptake and measure impact on: 1) heavy drinking; and 2) delivery of SBI in PHC.

Methods: Meta-analysis was conducted of controlled trials of SBI implementation strategies in PHC to reduce heavy drinking. Key outcomes included alcohol consumption, screening, brief interventions and costs in PHC. Predictor measures concerned single versus multiple strategies, type of strategy, duration and physician-only input versus that including mid-level professionals. Standardised mean differences (SMD) were calculated to indicate the impact of implementation strategies on key outcomes. Effect sizes were aggregated using meta-regression models.

Results: The 29 included studies were of moderate methodological quality. Strategies had no overall impact on patients' reported alcohol consumption (SMD 0.07;95%-CI -0.02-0.16), despite improving screening (SMD 0.53;95%-CI 0.28-0.78) and brief intervention delivery (SMD 0.64;95%-CI 0.27-1.02). Multifaceted strategies, i.e. professional and/or organisational and/or patient oriented strategies, seemed to have strongest effects on patients' alcohol consumption ($p<0.05$, compared to professional oriented strategies alone). Regarding SBI delivery, combining professional with patient oriented implementation strategies had the highest impact ($p<0.05$). Involving other staff besides physicians was beneficial for screening ($p<0.05$).

Conclusions: Strategies should include a combination of patient, professional and organisational oriented implementation approaches and involvement of mid-level professions as well as physicians. Evidence for a new and innovative combination of multiple implementation approaches to increase alcohol focused SBI uptake in PHC, is required.

Introduction

Worldwide, heavy alcohol consumption is a leading cause of ill-health and premature death.¹ World Health Organization (WHO) recommends that health professionals provide alcohol screening, brief interventions, counselling and, when necessary, pharmacotherapy for heavy drinkers.² There is a wealth of evidence in primary health care (PHC) for the effectiveness of alcohol screening and brief interventions (SBI) in adults.³⁻⁶ Previous research demonstrates that SBI is effective in various groups, either for identification of risky drinking, alcohol use disorders, excluding addicted patients, and for those who are not seeking treatment for alcohol-related problems.⁶⁻⁹ Brief interventions to reduce heavy drinking are cost-effective and could be widely available in PHC (3). However, SBI is underused with less than 10% of those who might benefit from SBI, receiving a brief intervention.¹⁰ Large-scale studies that have attempted to increase the uptake of brief interventions have shown that implementing brief interventions in PHC remains difficult.¹¹⁻¹³

Studies that address the issue of integrating evidence into practice are referred to as 'implementation research'.¹⁴ Changing provider behaviour and implementing new programs or innovations into practice could be achieved by various implementation strategies, as shown in the broader implementation literature.¹⁵⁻¹⁷ Promisingly, an increasing number of implementation studies are being conducted in the field of PHC-based alcohol prevention. In the last decade, three reviews have summarised the evidence to enhance the implementation of SBI in PHC.¹⁸⁻²⁰ These reviews found that the effectiveness of multi-component implementation programmes on SBI delivery showed the most promising results.²⁰ Effectiveness of implementation strategies on SBI delivery generally increased with the intensity of the intervention effort.¹⁹ Furthermore, it is suggested that nurses and other mid-level professionals, besides physicians, can enhance the uptake of SBI in PHC.²¹⁻²³

However, current literature provides little practical guidance on how to improve implementation. The impact of SBI on patients' alcohol consumption has been studied in many trials (e.g. ^{11,24,25}), but earlier systematic reviews did not provide practical guidance in how to increase SBI uptake in practice.^{4,6,7,26} More insight is needed on how the uptake of SBI in PHC practice can be increased to contribute to health benefits. Therefore, the current review aims to identify effective SBI implementation strategies that 1) reduce heavy drinking and 2) increase SBI delivered in PHC. The review will also ask if involving nurses and other professionals has a positive impact in improving SBI delivery and decreasing patient alcohol consumption.

Methods

This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) standards.²⁷ The review protocol is available from http://www.odhinproject.eu/resources/documents/cat_view/3-odhin-project-documents/6-technical-reports-and-deliverables.html.

We followed the Cochrane Effective Practice and Organisation of Care (EPOC) criteria, which define implementation strategies as “interventions designed to improve professional practice and the delivery of effective health services”. EPOC offers guidance on conducting reviews of interventions that improve professional practice and delivery of effective health services. To connect this study to broader implementation research, we used the EPOC search strategy, the EPOC template for data extraction, and the EPOC taxonomy to categorise implementation strategies, and their checklist for quality appraisal.²⁸

Data sources and searches

The following computerised databases were searched since onset until May 2013: MEDLINE, EMBASE, Cinahl and Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy is listed in Appendix 1. In addition, reference lists of relevant review articles and books were screened, and global experts in the field were contacted in order to identify grey literature and recent published studies not yet indexed.

Study selection

Two reviewers (MK and ML) independently screened relevant titles and abstracts. Full text copies of potentially relevant studies were then obtained and independently screened for inclusion by the same two reviewers. Disagreements between the reviewers were resolved through discussion, or a third reviewer was contacted to make the final decision (PA or IVDG).

In order to be included, a study had to meet the following PICO criteria²⁷: first, it had to be focused on a PHC setting; second, it had to include implementation strategies that were compared with a control group (usually defined as care as usual); third, it had to address decreasing heavy alcohol consumption, and/or cost outcomes, and/or increasing screening, and/or increasing brief interventions, but not alcohol dependence as defined by WHO²⁹ and the ICD-10 Classification of Mental and Behavioural Disorders³⁰; and, fourth, it had to be a controlled trial with an English or Dutch language full text copy available.

Effectiveness studies, e.g. examining the effectiveness of a 5-minute brief intervention compared to a 15-minute brief intervention, were excluded as they did not evaluate implementation strategies as defined by EPOC.

Data extraction and quality assessment

Data for each included study were extracted on: participants, setting, methods, SBI procedures, method of strategy, outcomes (alcohol consumption, screening, brief intervention, costs) and methodological quality. Implementation strategies were first classified into one of the following categories of the EPOC taxonomy: professional, financial, organisational, structural and regulatory interventions (<http://epoc.cochrane.org/epoc-taxonomy>); and, second, implementation strategies were classified into the EPOC elements, such as audit and feedback within professional oriented strategies.²⁸ Two reviewers in different combinations (MK, MBAS, DNB, EK, PA, ML, JB, and IVDG) independently extracted the data. Any disagreement was resolved by discussion or by asking a third reviewer (from the review team) when consensus was not reached between the two reviewers.

Methodological quality of each paper was assessed by both reviewers using the EPOC checklist for quality criteria.²⁸ Quality assessment was based on concealment of allocation, presence of professionals' behaviour or patient outcomes (alcohol consumption), follow-up, blinded assessment of primary outcome, baseline measurement of primary outcome, reliable (objective) primary outcome measures and protection against contamination. Any disagreement on fulfilling the criteria was resolved by discussion. Inclusion of studies was not influenced by methodological quality.

Data synthesis and analysis

All study outcomes were categorised by alcohol consumption, screening and/or brief interventions or costs, and type of implementation strategy. Methods described by the Cochrane Collaboration were followed.³¹

First, to identify effects of implementation strategies on the key outcomes, included studies were pooled with MetaEasy version 1.0.4.³² Standardised mean differences (SMD) were calculated, both for dichotomous and continuous outcomes. Due to heterogeneity of included studies, we estimated effect sizes using a random-effects model based on DerSimonian and Laird's (DL) approach.³³

Second, effect sizes of predictor measures, such as single versus multiple strategies, were calculated by meta-regression analyses. One advantage of such an approach is that, in case of no overall statistical effect being found from pooled studies, the regression allows distinction between effective and ineffective predictor measures. The predictor measures comprised 1) use of a single implementation strategy versus the use of multiple implementation strategies; 2) the type of implementation strategy as categorised by EPOC taxonomy²⁸, e.g. professional oriented strategies, such as audit and feedback, or organisational oriented strategies, such as task substitution; 3) whether or not the programme included multiple elements within their implementation strategy; 4) study duration ≤ 12 months versus study duration >12 months; and, 5)

whether the implementation strategies were focused on physician-only or those including nurses and other mid-level professionals. As instructed for fixed-effects meta-regression, we used weighted least squares regression, weighted by the inverse of the variance to identify relationships between predictors in explaining effect sizes.³⁴ A random-effects meta-regression was attempted, but did not converge. The cause of non-convergence was that the random effects of the predictors involved could not be estimated (probably because the number of studies was not sufficient to distinguish predictor random effects different from 0). Meta-regression was applied with use of SPSS version 20 [IBM SPSS Statistics, USA].

Results

Search results

Our literature search identified 4,594 citations, of which 3,968 unique titles and abstracts were screened (figure 1). The full paper sift included 211 papers. Included in this were eight published papers that were identified by manual review of the reference lists of the studies and consultation of global experts. In the second sift, reasons for exclusion were design failures (n=83), setting failures (n=42), not being focused on implementation (n=24) and not including alcohol consumption or SBI outcomes (n=29). Thirty-five papers, reporting on 29 studies were included in the final analysis.

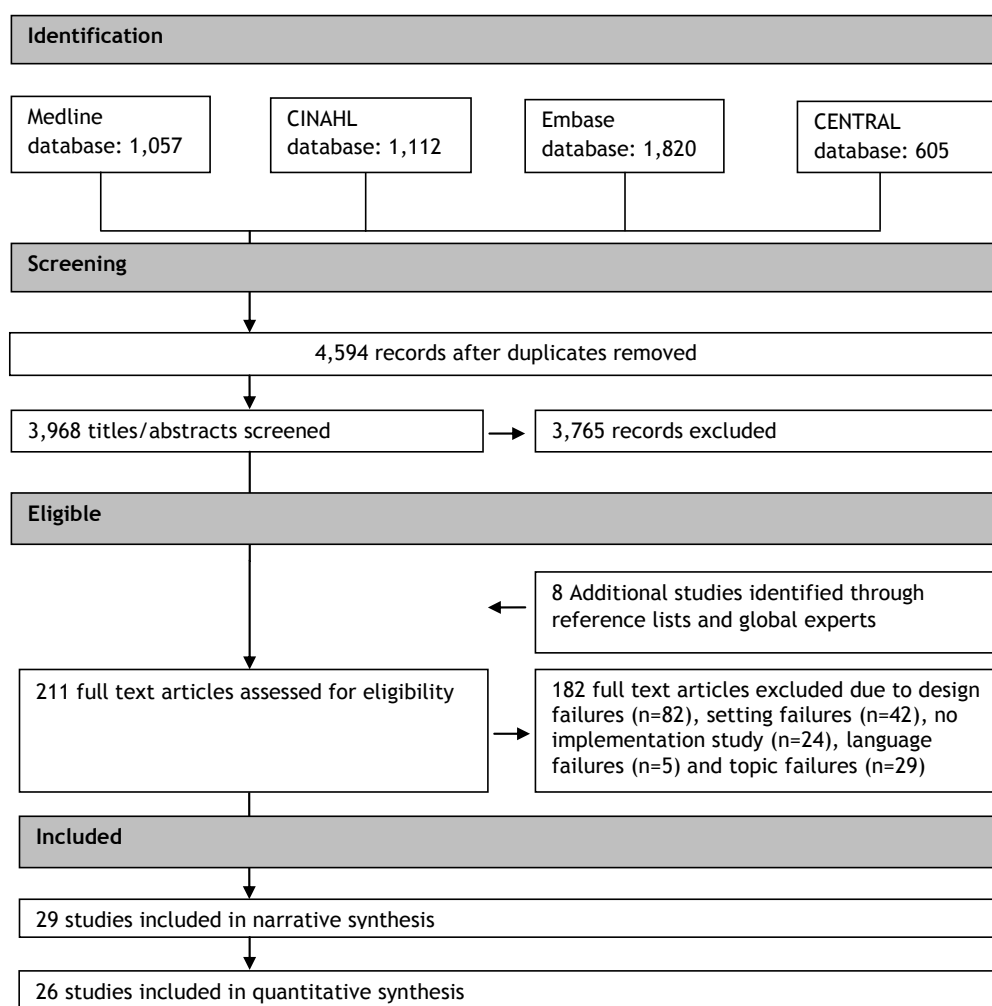
Methodological quality

All included studies were randomised controlled trials (RCT) (86%) or controlled clinical trials (CCT) (14%) (table 1). Concealment of allocation was not reported in eight studies (28%) and was not clear in seven studies (24%). In eight studies (28%), substantial differences across study groups were found, or no baseline measurements of primary outcomes were reported. Protection against contamination was not addressed in eleven studies (38%) and not clear in five studies (17%).

Study characteristics

Most studies were carried out in the United States, followed by Australia/New Zealand, Europe, and Canada (table 2). Participating professionals were physicians (16 studies), or physicians in combination with other PHC staff such as nurses (5 studies), nurse practitioners (2 studies), physician assistants (1 study), practice assistants (1 study) or other health professionals (1 study). In the remaining studies the profession of participating professionals was not reported. In over a half of studies (55%), the age of the patient groups ranged between 30-69 years. Other patient characteristics were not reported.

Figure 1. Flow chart of study selection



The included studies varied in applied implementation strategies and elements (table 1). The majority of studies (n=11) applied solely professional oriented implementation strategies.^{25,35-44} Most common elements were educational meetings (n=6), educational outreach visits (n=5) and audit and feedback (n=4). Three studies reported only organisational oriented strategies in which two applied a change in the scope and nature of benefits and services^{45,46}, and one applied a change in the service delivery due to counselling by phone⁴⁷. One further study reported a patient oriented strategy, which consisted of printed educational materials for patients.⁴⁸

Table 1. Quality scores of included studies, based on Cochrane Effective Practice and Organisation of Care checklist

Author year	Power calculation reported and sufficient	Unit of Allocation is unit of analysis or statistical correction for clustering	Concealment of allocation
Adams 1998	Not done	Done	Not clear
Beurden van 2012	Not clear	Done	Done
Bonevski 1999	Done	Done	Done
Borgiel 1999	Done	Not clear	Done
Bradley 2002	Not done	Not done	Not clear
Brown 2007	Done	Not done	Done
Butler 2003	Not done	Not done	Not done
Chossis 2007	Not clear	Done	Done
Drevenhorn 2012	Done	Not done	Not done
Ferrer 2009	Not done	Done	Done
Fink 2005	Not done	Done	Not clear
Friedmann 2006	Not done	Done	Not clear
Funk 2005	Done	Done	Done
Helzer 2008	Not done	Done	Not clear
Kaner 2003	Done	Not done	Not done
Kypri 2004	Done	Done	Done
Kypri 2005	Done	Done	Done
Kypri 2008	Not done (sample size not achieved)	Done	Done
Lockyer 1996	Not done	Done	Done
Oslin 2003	Not done	Done	Done
Oslin 2006	Not done	Done	Not clear
Reiff-Hekking 2005	Done	Done	Not done
Rodney 1985	Not done	Done	Not done
Rose 2008	Not done	Done	Not clear
Saitz 2003	Done	Done	Done
Vinson 2000	Not done	Done	Not done
Wang 2010	Not done (sample size not achieved)	Done	Done
Williams 201	Not done	Not done	Not done
Wilson 1992	Not done	Not done	Not done

Follow-up of professionals/ patients achieved	Blinded assessment of primary outcome(s)	Baseline measurement of primary outcome(s)	Reliable primary outcome measures	Protection against contamination
Not clear	Done	Not clear	Not clear	Not clear
Not done	Done	Done	Not done	Done
Done	Not done	Done	Not done	Done
Done	Not done	Done	Not done	Not done
Not done	Done	Not done	Not clear	Done
Done	Done	Done	Not clear	Not done
Not clear	Not done	Done	Not done	Done
Done	Not done	Done	Not done	Not clear
Prof: not done ; patients: done	Not clear	Not done	Not clear	Not done
Done	Not done	Not done	Done	Not done
Done	Not done	Done	Done	Not clear
Not clear	Not clear	Not clear	Not clear	Not done
Done	Not clear	Not done	Done	Done
Done	Not done	Done	Not clear	Not done
Not done	Not done	Not done	Not clear	Done
Done	Not done	Done	Done	Done
Done	Done	Not clear	Done	Done
Done	Not done	Not clear	Not done	Not clear
Done	Not done	Done	Not done	Not done
Done	Not clear	Done	Not clear	Done
Done	Done	Done	Done	Not clear
Done	Not done	Not clear	Not done	Done
Not clear	Not done	Not done	Not clear	Not done
Not clear	Not done	Done	Not done	Done
Done	Not done	Done	Not clear	Done
Done	Not done	Done	Not done	Done
Not done	done	Not done	Not done	Not done
Done	Not clear	Not done	Done	Not done
Not done	Done	Done	Done	Not done

In addition, six studies reported a combination of professional oriented and organisational oriented implementation strategies, in which in all educational meetings were applied, combined with either changes in medical record systems, formal integration of services or skill mix changes.⁴⁹⁻⁵⁴ Eight studies reported various combinations of professional oriented, organisational oriented, patient oriented and financial oriented strategies.^{11,23,24,55-59}

Nineteen studies reported patient alcohol consumption outcomes.^{11,23,24,35,38,43-45,47,48,50-53,55-59} Studies reported one or more professional-related outcomes, that is: screening rate (n=12)^{11,25,35-37,39-42,46,49,54} and brief intervention (BI) rate (n=13)^{11,23,25,37-43,46,49,50}. Only two studies reported outcomes related to costs or cost-effectiveness (table 3).^{40,41}

Table 2. Characteristics of included studies

Study, ref	Design, study duration	Setting (country; setting; type of health care professionals)	Participants
<i>Professional oriented implementation strategies</i>			
Bonevski ³⁵	RCT, study duration assumed to be 5 months	Australia Primary health care practice GPs	General practitioners N=19 Patients N=575 (Group 1 N=154; Group 2 N=143; Group 3 N=138; Group 4 N=140)
Borgiel et al ³⁶	RCT, study duration 2 years	Canada Primary health care practice Physicians	Family physicians N=56 (Intervention group N=29; Control group N=27)
Bradley et al ³⁷	CCT, study duration 6 months	United States Primary health care practice Resident or fellow MD, Faculty/staff MD, family nurse practitioner	General internal medicine clinic N=17 (6 resident or fellow MDs; 6 faculty/staff MDs; 5 family nurse practitioners); Patients N=47 (Intervention group N=17; Control group N=30)
Chossis et al ³⁸	RCT, study duration assumed to be 9 months	Switzerland Outpatient clinic (i.e. ambulatory care provided by specialists/hospitals) GPs	Primary health care residents N=26 (Intervention group N=13; Control group N=13)
Friedmann et al ³⁹	RCT, study duration 2 years	United States Primary health care practice GPs (15 physicians and 3 mid-level clinicians)	Physicians N=18 (Intervention group N= 12; Control group N=6)
Funk et al ⁴⁰ (including secondary studies ⁶⁹⁻⁷¹)	RCT, study duration unknown, implementation period of 12 weeks	Australia, New Zealand, England, Belgium, Catalonia, Denmark; Primary health care practice; GPs	General practitioners N=727 (Intervention group 1 N=255; Intervention group 2 N=263; Control group N=209)
Kaner et al ⁴¹	RCT, study duration 3 months	United Kingdom; Primary health care practice; Nurses	Practices N=128. (Intervention group 1 N=50; Intervention group 2 N=48; Control group N=30). N participating nurses unclear.
Lockyer et al ⁴²	RCT, study duration assumed to be 4 months	Canada; Primary health care practice; Family physicians and general practitioners	Family physicians and general practitioners N=54 (Intervention group N=26; Control group N=28)
Rose et al ⁴³	RCT, study duration 2 years	United States; Primary health care practice; Assumed to be GPs	22 practice units (Intervention group N=11; Control group N=11). N individual professionals not clear
Saitz et al ⁴³	RCT, study duration 1,5 years	United States; Primary health care practice; GPs	Faculty and resident primary health care physicians N=41 (Intervention group N=20; Control group N=21). Patients N=312 (Intervention group N=168; Control group N=144)

Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI) [#]
IS: Computerised feedback about: guidelines and consensus standards of care, individual goals, calculated performance rates. Practitioner feedback about patients' smoking status, benzodiazepine use, blood pressure screening, cholesterol screening, and the delivery of programme elements (Audit and feedback) ^a ; Control: Usual care	Screening: z=2.3079 (p<0.02)
IS: Practice assessment report, continuing Medical Education with additional plan and follow-up visit by mentors (Audit and feedback; educational meeting; educational outreach visits) ^b ; Control: Usual care	Screening: NR (p>0.05)
IS: Educational meeting; feedback report (Audit and feedback; educational meeting) ^b ; Control: Professional oriented: Single educational meeting	Screening: NR (p<0.005) BI: NR (p=0.035)
IS: Two educational meetings on an interactive Brief Alcohol Intervention, with theory, role-play exercises, checklists, and a textbook. Educational materials for professionals handing out to the patient (Educational meetings; educational materials) ^b ; Control: Professional oriented: Lipid management workshop, including alcohol use	BI: NR (p>0.05) Alcohol consumption: NR (p>0.05)
IS: Three educational meetings (initial training about the care model, a luncheon 6 weeks later, a booster training session 6 months later. Educational materials clipped to the charts of eligible patients (Educational meetings; reminders) ^b ; Control: Usual care	Screening: OR 2.8 (1.3 - 5.8) BI: OR -0.15 (-0.26 - -0.06)
Two IS's. IS 1: Outreach training session relating to a brief intervention programme (Educational outreach visits) IS 2: Outreach training session relating to a brief intervention programme and ongoing support and advice regarding programme implementation issues through biweekly telephone calls (England) and/or practice visits (Australia) (Educational outreach visits) ^a ; Control: Usual care	Screening: NR (p<0.005) BI: NR (p<0.001) cost-effectiveness ^y
Two IS's. IS 1: Educational outreach visits about the programme, SBI procedures and practical problems (Educational outreach visits) IS 2: Same educational outreach visits as above + two-weekly telephone calls for support and advice (Educational outreach visits) ^a Control: Professional oriented: written implementation guidelines	Screening: NR (p=0.0025) BI: p=0.025 costs; cost-effectiveness ^y
2 intervention groups. Group 1: family physicians; Group 2: general practitioners. IS: Educational programme: one day education including visits to five local treatment facilities and their therapeutic programs; and three evening sessions (Educational meetings; educational outreach visits) ^b Control: Assumed to be usual care.	Screening: F [2,49]=4.82 (p<0.033) BI: F [2,49]=16.69 (p<0.001)
IS: Written materials, on site academic detailing, performance feedback through practice reports, network meetings (Distribution of educational materials; educational outreach visits; audit and feedback; educational meetings) ^b ; Control: Professional oriented: written materials.	Screening: OR 8.1 (1.7-38.2) BI: OR 5.5 (1.3-23.3)
IS: Feedback patients' alcohol screening results to physicians with recommendations (Patient mediated interventions) ^a ; Control: Usual care	BI: NR Alcohol consumption: NR

Study, ref	Design, study duration	Setting (country; setting; type of health care professionals)	Participants
Williams et al ⁴⁴	RCT, study duration 3 years	United States; Outpatient clinic; Physicians, residents, nurse practitioners physician assistants	Physicians, residents, nurse practitioners, and physician assistants (N= not clear) Patients N = 1,358 (Intervention group N=692; Control group N=666)
<i>Organisational oriented implementation strategies</i>			
Brown et al ⁴⁷	RCT, study duration 12 months	United States; Primary health care practice; Counsellors. Type of health care professionals not reported	Patients N= 897. Sub set of n=472 patients with alcohol abuse (Intervention group n=231; Control group: n=241)
Vinson et al ⁴⁵	RCT, study duration 12 months	United States; Primary health care practice; GPs	Patients N=80 (N participants per group not reported)
Wilson et al ⁴⁶	CCT, study duration not clear	United Kingdom; Primary health care practice; GPs	Physicians N=16. Allocation at the level of days/sessions (N sessions Intervention group N=1,411; Control group 1 N=1,478; Control group 2 N= 1,432)
<i>Patient oriented implementation strategies</i>			
Wang et al ⁴⁸	RCT, study duration 1 month	United States; Emergency department setting	Patients N=252 (Intervention group N=95; Control group N=93)
<i>Professional and organisational oriented implementation strategies</i>			
Adams et al ⁴⁹	RCT, study duration 32 months	Assumed to be in United States; Primary health care practice; Physicians, nurses	Physicians N=21; Resident N=1 resident; Nurse practitioners N=7; Patients N=344 (Inter-vention group N=200; Control group N=144)
Ferrer et al ⁵⁰	RCT, study duration median time = 360 days (range 159-565; 10th percentile 215; 90th percentile 441)	United States; Primary health care practice; GPs and medical assistants	GPs (N unclear); Medical Assistants (N=100); Patients N=864 (Inter-vention group N=437 of which N=57 drinking; Control group N=427 of which N=67 drinking)
Oslin et al ⁵²	RCT, study duration 24 weeks	United States; General practice/ primary health care clinic/ family practice Clinicians	Clinicians from different primary health care settings N=37; patients N=97 (Intervention group; N=46 control group N=51)
Oslin et al ⁵¹	RCT, study duration 9 months	United States; Primary health care practice; and Community based care/ community health centres	Patients N=560 (Intervention group 1 N= 227; Intervention group 2 N= 239; no control group)

Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI) [#] ;
IS: Reminder for primary health care provider after patients' positive alcohol screen; e-mail alerts to professionals (Reminders) ^a Control: Assumed to be usual care	Alcohol consumption: NR (p>0.25)
IS: Delivery of counseling via telephone and mail (Changes to the setting/ service delivery) ^a ; Control : Usual care	Alcohol consumption: NR (p>0.05)
IS: Computer-Generated Written Behavioural Contracts. Physician reviewed the contract briefly with the patient, signed it, and encourage compliance with its terms (Changes in scope and nature of benefits and services) ^a ; Control: Usual care	Alcohol consumption: 0.34 (p>0.05)
IS: Expanding consultation time from on average 7.5 minutes to 10 minutes per patient. Control group 1: matched for time of day and day of the week, drawn from the period before the trial (Changes in scope and nature of benefits and services) Control group 2: matched for time of day and day of the week, during the trial phase, in the alternate weeks when an experimental session was not scheduled (Changes in scope and nature of benefits and services) ^a	Screening: 1-NR (p<0.05) 2-NR (p>0.05) BI: 1:NR (p<0.001) 2:NR (p<0.01)
IS: Subjects in the intervention group were given a brochure titled, "Alcohol, How Much is Too Much?" (Printed educational materials for patients) ^a ; Control: Assumed to be usual care	Alcohol consumption: NR (p=0.95)
IS: Educational meetings: Training in motivational interviewing and topics about alcohol (2,5 hours). + intervention algorithm (Educational meetings; changes in medical record system) ^b ; Control: Usual care	Screening: NR (p<0.001) BI: NR (p<0.001)
IS: Professional role revision: assessments and referrals were performed by medical assistants; Educational meetings: three training sessions about how to assess, inform, encourage and refer patients (Educational meetings; Skill mix changes) ^b ; Control: Usual care	BI: NA alcohol consumption: NR (p>0.05)
IS: Patient Telephone disease management by a behavioural health specialist + educating professionals (Skill mix changes; educational meetings) ^b ; Control: Usual care	Alcohol consumption: OR=0.28 (p=0.142)
Two IS's, no control group. IS1. Integrated care model: participants receive mental health or substance abuse services in the primary health care clinic from a mental health or substance abuse provider + education (Educational meetings) IS2. Enhanced specialty referral model includes referral from primary health care and provides mental health or substance abuse services in a specialty mental health or substance abuse clinic (Educational meetings; formal integration of services) ^b	Alcohol consumption: MD - 0.1 (-2.5- 2.2; p=0.913)

Study, ref	Design, study duration	Setting (country; setting; type of health care professionals)	Participants
Reiff-Hekking et al ⁵³ (including secondary study ⁷²)	RCT, study duration 3 years	United States; Ambulatory primary health care setting; Physicians; nurses	Physicians N=38; Nurses N=8; Patients N=530 (Intervention group N=248; Control group N=233)
Rodney et al ⁵⁴	CCT, study duration 5 years	United States; Primary health care practice; Physicians, Nurses, Psychologist, social worker, dietician	Physicians N= assumed to be 22 residents (medicine) and 32 family physicians; Nurses N=2; Psychologist N=1; licensed clinical social worker N=1; dietician N=1; Patients N=390 (Intervention group N=114; Control group N=110)
<i>Professional and patient oriented Implementation strategies</i>			
Drevenhorn et al ²³ (secondary study included ⁷³)	RCT, study duration 2 years	Sweden; ? Nurses	Nurses N=33 (intervention group N=19; Control group N=14). Patients N=213 (Intervention group N=153; Control group N=60)
Fink et al ⁵⁷	RCT, study duration 2,5 years	United States; Primary health care practice; Physicians	Physicians (N= not clear) and patients N=665 (Intervention group 1 N= 245; Intervention group 2 N=198; Control group N=222)
<i>Organisational and patient oriented implementation strategies</i>			
Kypri et al ⁵⁹	RCT, study duration 6 months	New Zealand; Community based care/ community health centres	Patients N=104 (Intervention N=42; Control N=41)
Kypri et al ⁵⁸	RCT, study duration 6 weeks	New Zealand; General practice/ primary health care clinic/ family practice	Patients N=218 (Intervention Group 1: N=72; Intervention Group 2 N=74; Control: N=72)
Kypri et al ²⁴	RCT, study duration 12 months	New Zealand; General practice/ primary health care clinic/ family practice	Patients N=429 (Intervention Group 1: N=138; Intervention Group 2: N=145; Control: N=146)

Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI) [#] ;
IS: Training; Individual tutorial (including education materials); role-play; office support system (lifestyle interview summary sheet; intervention algorithm) (Educational meetings; educational materials; changes in medical record system) ^b Control: Professional oriented: Encouraged to identify and intervene with patients with alcohol related issues; Encouraged to attend weekly conference series	Alcohol consumption: NR (p=0.03)
IS: Education, educational materials + reminders (face sheet on record) (Educational meetings; educational materials; reminders; changes in medical record systems) ^b Control: Professional and organisational oriented: year 1-3: similar intervention group. Year 4-5: chart review sessions in which residents reviewed three to five of their records during July, November and April	Screening: NR (p>0.05)
IS: educational outreach visits, with education in stages of change, Motivational Interviewing and applying guidelines for cardiovascular prevention, lifestyle factors and pharmacological treatment. Distribution of educational materials for nurses. Educational materials for patient to support patients' self-management (Educational outreach visits; Distribution of educational materials; Patient self-management education materials) ^b ; Control: Usual care	BI: NR Alcohol consumption: NR
Two IS's. IS1: Combined report, in which physicians and patients received reports of patients' drinking classifications and patients also received education (Patient mediated interventions; patient feedback; patient education); IS2: Patient report, in which patients received reports and education, but their physicians did not receive reports (patient feedback; patient education) ^b ; Control: Usual care	Alcohol consumption: NR (1:p<0.05, 2:p>0.05)
IS: Web-based screening and brief intervention including patient feedback (changes to the setting/ site of service delivery; patient feedback) ^b ; Control: Organisational oriented: 'Alcohol Facts and Effects' leaflet was given by the research assistant	Alcohol consumption: Ratio of geometric means 0.80 (0.63-1.02; p0.08)
Two IS's. IS1. Computerised assessment + feedback and advice on patients' fruit and vegetable consumption, physical activity, alcohol consumption, and smoking (changes to the setting/ site of service delivery; patient feedback) ^b IS2. Computerised assessment only Control: Untargeted activity: Minimal contact at baseline	Alcohol consumption: F = 0.208 (p=0.813)
Two IS's. IS1. Web-based motivational intervention (changes to the setting/ site of service delivery) IS2. Web-based motivational intervention with further interventions 1 and 6 months later (including personalised feedback) (changes to the setting/site of service delivery; patient feedback) ^b Control: Patient oriented: Information pamphlet on health effects of alcohol consumption	Alcohol consumption: 1(6months):Rate ratio 0.79 (0.68-0.94), 2(6months):Rate ratio 0.85 (0.73 to 1.00), 1(12 months): Rate ratio 0.86 (0.74-1.01), 2(12months): Rate ratio 0.92 (0.79-1.07)

Study (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants
<i>Professional, organisational and patient oriented implementation strategies</i>			
Van Beurden et al ¹¹ (secondary study included ⁷⁴)	RCT, study duration 2 years	Netherlands; Primary health care practice; GPs	General practitioners N=119 (Intervention group N=47; Control group N=47); Patients N=712 (Intervention group N=346; Control group N=366)
<i>Organisational, patient and financial oriented implementation strategies</i>			
Butler et al ⁵⁶	CCT, study duration not clear	United States; Primary health care practice; Physicians, nurse practitioners, nurses, practice assistants	Physicians N=33; Nurse practitioners N=7; Nurses N=5; Practice assistants N=3 (Intervention group professionals N=62; Control group professionals N=66); Patients (N=2053)
Helzer et al ⁵⁵	RCT, study duration 6 months	United States; Primary health care practice; Type of healthcare professionals not reported	Care professionals (profession not reported) N=112 (Intervention group 1 N=75; Intervention group 2 N=75; Intervention group 3 N=53; Control N=81); Patients N=338

[#]CI = confidence interval; OR = odds ratio; RCT = randomized controlled trial; CCT = controlled clinical trial; NA = not applicable; NR = not recorded; SBI = screening and brief intervention; BI = brief intervention; *outcome types could be screening, brief intervention, alcohol consumption

Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI) [#] ;
<p>IS: Distribution of the guideline; a reminder-card to display on the GPs desk; educational training session tailored to professionals' attitudes; feedback report on patient alcohol consumption risk level; facilitation of the cooperation with local addiction services for support and referral; outreach visits by a trained facilitator tailored to needs of practice; patient information letters, leaflets and self-help booklets about alcohol offered to general practices to be distributed to patients; poster in the waiting room; personal feedback to the patient based on their alcohol consumption risk category (Distribution of educational materials; educational meetings; reminders; audit and feedback; formal integration of services; educational outreach visits; patient feedback)^b</p> <p>Control: Guidelines were mailed to GPs; information letters about problematic alcohol consumption were sent to patients. Patients also received personal feedback on alcohol consumption after closure of the intervention period.</p>	<p>Screening:NR (p=0.60)</p> <p>BI: NR (p=0.57)</p> <p>Alcohol consumption: NR (p=0.01 in opposite direction)</p>
<p>IS: Computerised health assessment, and training how to use this, and tailored feedback to patients (Educational outreach visits; changes to the setting/ service delivery; patient feedback)^b; Control: Usual care</p>	<p>Alcohol consumption: NR (p>0.05)</p>
<p>Three IS's.</p> <p>IS1: Daily phone calls for 6 months to an automated Interactive voice response system to report alcohol consumption (Changes to the setting/ service delivery)</p> <p>IS2: As group 1 + monthly patient feedback (Changes to the setting/ service delivery; patient feedback)</p> <p>IS3: As group 2 + financial compensation based on frequency of participants' daily calls (Changes to the setting/ service delivery; provider incentives; patient feedback)^b</p> <p>Control: Usual care</p>	<p>Alcohol consumption: NR</p>

Table 3. Reported cost outcomes

Author, ref	Elements	Unit of outcome reporting	Outcome intervention	Outcome control	Effect	p-value or CI-95%
<i>Professional oriented interventions</i>						
Funk et al ⁴⁰ (including secondary studies ^{69,71})	Educational outreach visits	Cost per GP giving at least one intervention				
		Provider level - materials and instructions only			£74.29	
		Provider level - one educational outreach visit			£92.80	
		Provider level - one educational outreach visit and six telephone support contacts			£128.92	
		Cost per patient advised				
		Patient level - materials and instructions only			Aus\$ 3.51	
		Patient level - one educational outreach visit			Aus\$ 2.16	
		Patient level - one educational outreach visit and six telephone support contacts			Aus\$ 4.33	
		Cost per patient advised				
		Patient level - materials and instructions only			£8.19	
		Patient level - one educational outreach visit			£6.02	
		Patient level - one educational outreach visit and six telephone support contacts			£5.43	
		Median number of patients screened				
		Full cost for trained practice: £157		Full cost of promoting and implementing SBI £93 per practice		
Kaner et al ⁴¹	Educational outreach visits		Full cost for trained and supported practice £163	When full costs of GP-led SBI were considered, nurses were more cost-effective at delivering brief interventions. However, if just promotional costs were considered, GPs' were more cost-effective.		p<.001

SBI = screening and brief interventions, GP = general practitioner

Elements of effective implementation strategies

Twenty-six studies were pooled and 24 studies were included in the meta-regression.

Effects on alcohol consumption

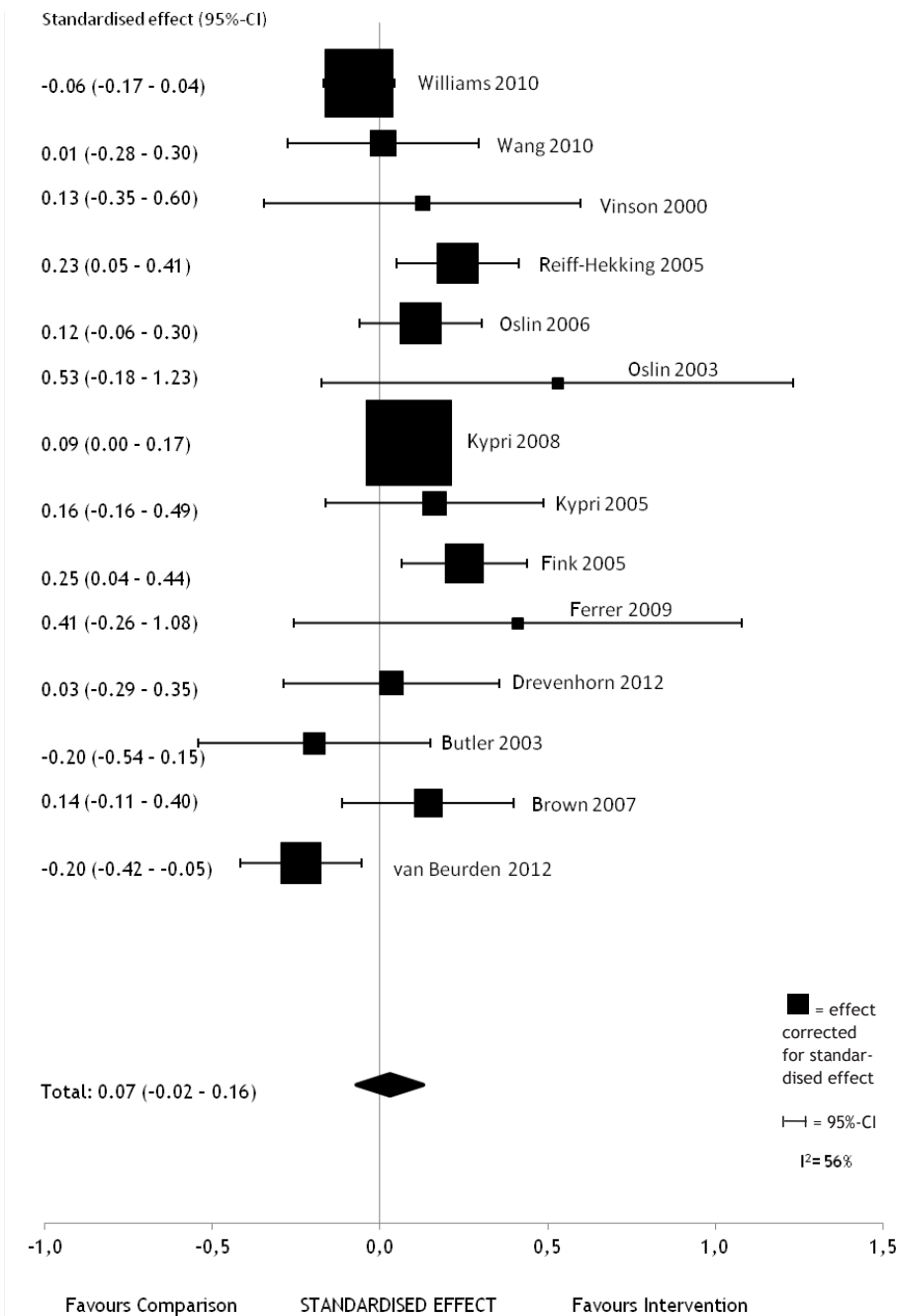
Of the 19 studies reporting on alcohol consumption, 15 were pooled for an overall effect size.^{11,23,24,44,45,47,48,50-53,56-59} Due to substantial heterogeneity ($I^2 = 86\%$), we applied a random effects model. The random effects model showed no statistically significant effect of the pooled estimate of implementation strategies on alcohol consumption (SMD DL model -0.02; 95%-CI -0.17 - 0.14) (figure 2). One study, Kypri et al 2004⁵⁹ identified very strong opposite effects in a negative direction, meaning increased alcohol consumption, which was different to most other included studies. This could be due to the unique outcome measure used in the study (alcohol consumption in the last two weeks), whereas the rest of the studies reported on changes in drinking classification, AUDIT screening test scores, or mean weekly alcohol consumption, which are more representative measures. Using a post-hoc analysis without Kypri et al 2004 resulted in decreased heterogeneity ($I^2 = 56\%$). Still, no significant difference in pooled effect was found, compared to control groups (SMD DL model 0.07; 95%-CI -0.02 - 0.16) (figure 2). However, the remaining heterogeneity can be primarily explained by the type of implementation strategy, as presented from the meta-regression results in table 4 (omitting Kypri et al 2004). Table 4 shows that combinations of professional, organisational and patient oriented strategies were significantly more effective at decreasing patients' alcohol consumption than solely professional oriented implementation strategies (table 4).

Table 4. Meta-regression analysis: predictor variable effects on alcohol consumption based on 21 outcomes from 14 studies

Comparison	B	95%-CI	p-value
1. Single implementation strategy	-0.022		
Multiple implementation strategy	0.108	-0.068 - 0.284	0.206
2.* Organisational oriented	0.202	-0.014 - 0.417	0.063
Patient oriented	0.071	-0.193 - 0.336	0.543
Professional+organisational oriented	0.258	0.116 - 0.400	0.004
Professional+patient oriented	0.258	0.091 - 0.426	0.008
Organisational+patient oriented	0.154	0.037 - 0.271	0.017
Professional+organisational+patient oriented	-0.165	-0.332 - 0.002	0.053
3. Single component strategy	-0.022		
Multiple component strategy	0.108	-0.068 - 0.284	0.206
4. Study duration ≤ 12 months	0.056		
Study duration 12 months or longer	-0.046	-0.361 - 0.270	0.758
5. Physician participants only	0.019		
Physician participants combined	-0.011	-0.408 - 0.386	0.947

* Professional oriented implementation strategy was the reference category

Figure 2. Random effects meta-analysis of studies with alcohol consumption outcomes (excluding Kypri 2004)



Effects on SBI

Of the twelve studies with outcomes on screening, ten provided sufficient data for pooling.^{11,25,35-37,39,42,46,49,54} Due to high heterogeneity ($I^2=94\%$), we applied a random effects model (figure 3). Pooling showed that the implementation strategies increased screening delivery (SMD DL model 0.53; 95%-CI 0.28-0.78). Wilson et al (1992)⁴⁶ showed the least positive effect and Adams et al⁴⁹ the strongest positive effect. Studies with significant effects included both physicians and other health professionals (such as nurses) in screening for alcohol consumption more so than studies with little effect.

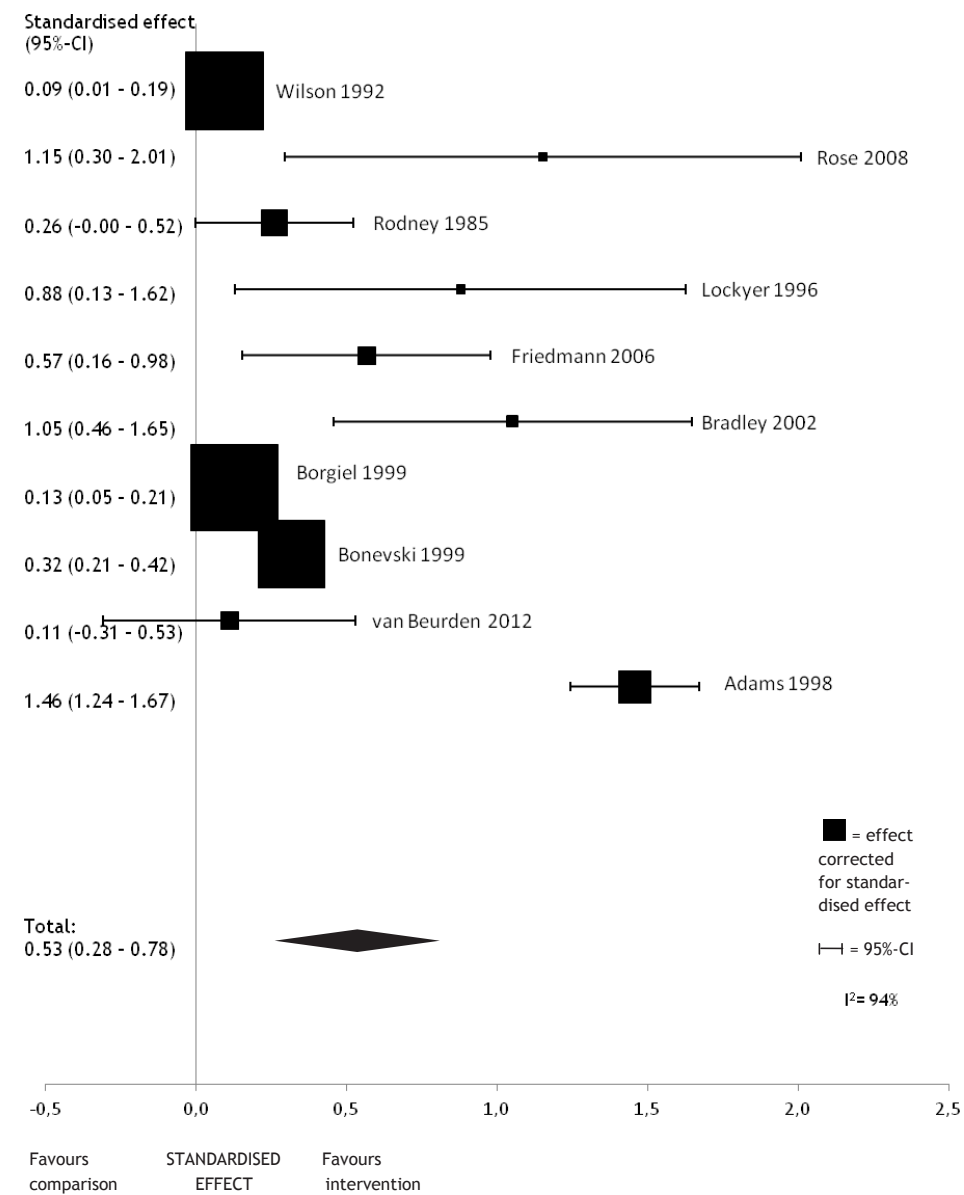
The meta-regression analysis (table 5) showed that multiple types of implementation strategies (e.g. professional combined with organisational oriented implementation strategies) were more effective in changing behaviour compared to a single implementation strategy (e.g. only a professional oriented implementation strategy). Furthermore, we found that combining professional and patient oriented strategies was more effective than only professional oriented strategies. Lastly, involving nurses and other mid-level professionals as well as physicians in implementation strategies, showed statistically significant higher effects than focusing on physicians only.

Table 5. Meta-regression analysis: predictor variable effects on screening based on 11 outcomes from 10 studies

Comparison	B	95%-CI	p-value
1. Single implementation strategy	0.158		
Multiple implementation strategy	0.675	0.021 - 1.330	0.044
2.* Organisational oriented	-0.129	-0.457 - 0.119	0.358
Professional+organisational oriented	0.034	-0.774 - 0.841	0.919
Professional+patient oriented oriented	1.231	0.562 - 1.900	0.005
Professional+organisational+patient oriented	-0.114	-1.383 - 1.156	0.827
3. Single component strategy	0.192		
Multiple component strategy	0.121	-0.380 - 0.623	0.591
4. Study duration ≤ 12 months	0.349		
Study duration 12 months or longer	-0.051	-0.725 - 0.622	0.862
5. Physician participants only	0.168		
Physician participants combined	0.767	0.24-1.295	0.010

* Professional oriented implementation strategy was the reference category

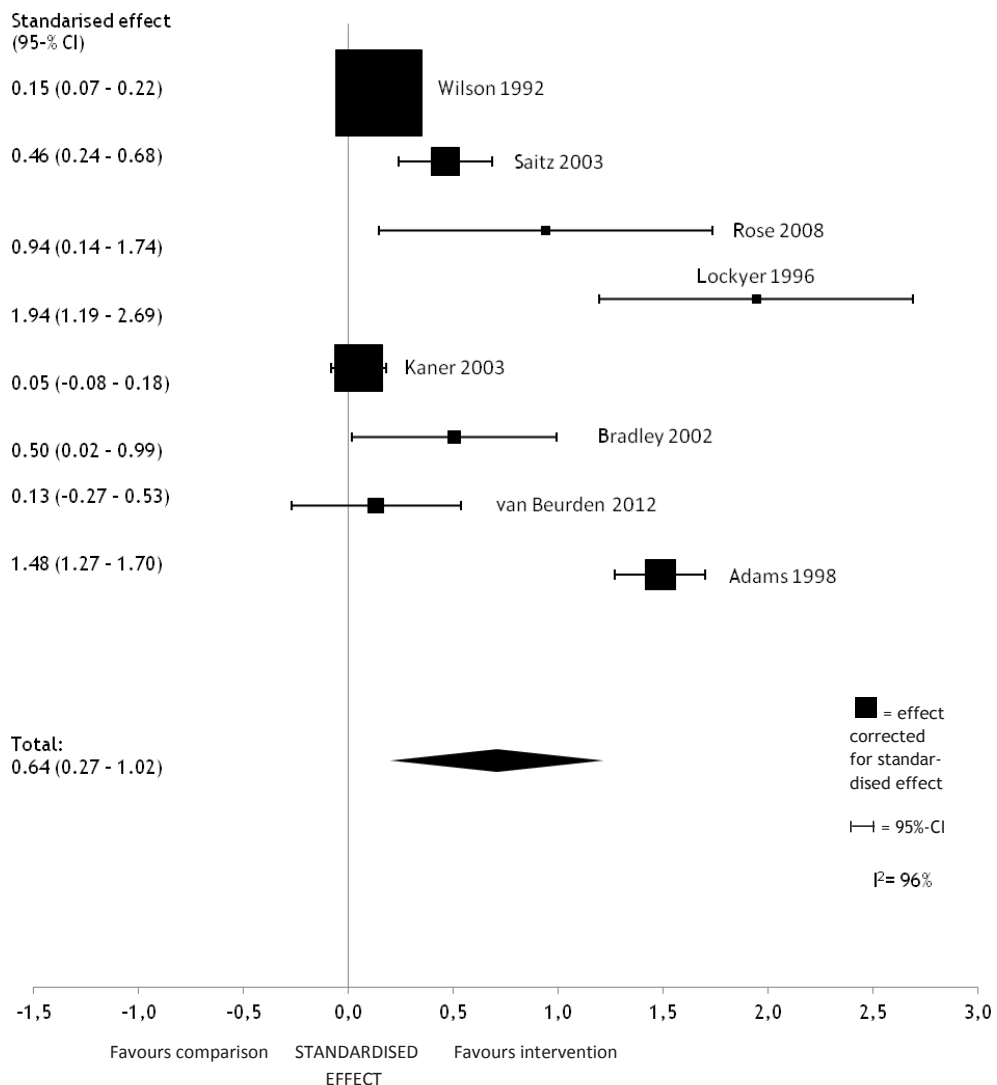
Figure 3. Random effects meta-analysis of studies with screening outcomes



With regard to the 13 studies that reported process outcomes on brief interventions, outcomes of nine studies were pooled.^{11,25,37,41-43,46,49,50} These studies showed high heterogeneity ($I^2=97\%$). Ferrer et al (2009)⁵⁰ was the only study in which patients had

the opportunity to choose which lifestyle topic to tackle (alcohol, smoking, physical activity or diet). The majority of patients preferred to discuss lifestyle factors other than alcohol. This approach was judged to be substantially different from the other studies. Therefore this study was not included in the analysis and forest plot (figure 4). The forest plot shows that the implementation strategies resulted in increased brief intervention delivery (SMD DL model 0.64; 95%-CI 0.27 - 1.02).

Figure 4. Random effects meta-analysis of studies with brief intervention outcomes (excluding Ferrer 2009)



The meta-regression analyses showed that multiple inclusion of implementation strategies was more effective than single types (table 6). Furthermore, the combination of professional and patient oriented implementation strategies, multiple component strategies and study duration of twelve months or more were of added value.

Table 6. Meta-regression analysis: predictor variable effects on brief interventions based on 10 outcomes from 8 studies

Comparison	B	95%-CI	p-value
1. Single implementation strategy	0.169		
Multiple implementation strategy	1.018	0.165 - 1.871	0.027
2.* Organisational oriented	-0.077	-0.630 - 0.477	0.720
Professional+patient oriented	1.262	0.243 - 2.281	0.026
Professional+organisational+patient oriented	-0.091	-1.868 - 1.686	0.893
3. Single component strategy	0.147		
Multiple component strategy	0.985	0.310 - 1.660	0.012
4. Study duration ≤ 12 months	-0.121		
Study duration 12 months or longer	1.003	0.023 - 1.983	0.046
5. Physician participants only	0.189		
Physician participants combined	-0.089	-0.882 - 0.703	0.797

* Professional oriented implementation strategy was the reference category

Discussion

This study aimed to identify implementation strategies that focused on increasing SBI uptake with an impact on patient alcohol consumption and/or SBI delivery in PHC. The predictor measures comprised: 1) use of a single implementation strategy versus the use of multiple implementation strategies; 2) the type of implementation strategy as categorised by EPOC taxonomy²⁸, e.g. professional oriented strategies such as audit and feedback, or organisational oriented strategies such as task substitution; 3) whether or not the programme included multiple elements within their implementation strategy; 4) study duration ≤ 12 months versus study duration >12 months; and 5) whether the implementation strategies were focused on physicians or on nurses and other mid-level professionals as well.

From the meta-analysis, it can be concluded that with all implementation strategies pooled, there was a lack of statistically significant impact on patients' self-reported alcohol consumption, although professional SBI behaviour improved. However, those specific studies that combined two of the professional, patient and organisational implementation strategies were significantly more effective in reducing alcohol consumption than solely professional oriented implementation strategies. This shows that it does matter which implementation strategy is selected. Regarding screening, combining professional with patient oriented strategies and involving primary health care staff besides physicians (e.g. nurses as well as physicians), led to increased activity. In terms of brief intervention delivery, implementation strategies had more

effect when multiple components of different implementation strategies were applied, for example combining educational outreach visits (professional oriented) with patient self-management education materials (patient oriented).

In line with the wider alcohol-related literature, our study confirms that multi-component programs seemed to be the most promising implementation strategies.²⁰ Our study added to this finding by identifying specific predictor variables for successfully changing provider SBI activity or patients' alcohol consumption behaviour, such as effectiveness of combining professional and patient oriented strategies. Similar to Nilsen et al.¹⁹ and Williams et al.¹⁸, this present study showed that the implementation strategy effectiveness generally increased with the intensity of the implementation effort, a finding different from general implementation research⁶⁰. We have added to this general finding by identifying elements that made the implementation strategies more effective, such as combining professional, patient and organisational implementation strategies.

Furthermore, the present study demonstrates that, in order to increase screening behaviour, involving nurses and other mid-level professionals is more effective than focusing only on physicians delivering the screening, which is in line with other studies in PHC.^{21,22,61}

Whereas reviews³⁻⁷ find significant reductions in alcohol consumption from implemented SBI, this positive effect was not found in our meta-analyses, which focused on strategies to increase SBI uptake and not on SBI effectiveness itself.⁶² We found that multiple implementation approaches have a significant impact in increasing SBI delivery, but not on reducing patient alcohol consumption. The marginal benefits of additional services provided through multiple implementation approaches are low. Therefore, new and innovative combinations of multiple implementation approaches are required to increase SBI uptake in primary health care. It is possible that the delivered brief interventions might have been suboptimal in the included studies, resulting in less reduction in patients' alcohol consumption as potentially could be achieved.⁶³ Low fidelity in delivering lifestyle-changing interventions have been reported in several other studies.^{61,64,65} However, we were not able to correct for this assumption as included studies did not report on fidelity of the intervention. Finally, another reason for failing to find effects of implementation strategies on alcohol consumption is that studies may have lacked sufficient power to detect significant differences; we found that half of the included studies did not report on or achieve sufficient power.

A strength of our study includes the categorisation of interventions defined by the EPOC taxonomy of interventions²⁸, as uniform analysing and reporting methods prevents confusion about terminology, and contributes to the evidence base of implementation strategies.¹⁶ There are alternatives to the pragmatically-funded EPOC taxonomy with more theoretical fundamentals, including the Behaviour Change Wheel, Leeman

Taxonomy and Behaviour Change Techniques⁶⁶; however, these more recent developed taxonomies are based on the EPOC taxonomy.⁶⁷

Another strength of our study is that it is the first systematic review that included a meta-regression analysis regarding implementation strategy outcomes on subsequent patient alcohol consumption. Nevertheless, the meta-analysis should be interpreted with caution as the standardised mean differences cannot give quantitative outcomes that could be easily translated into daily practice. Moreover, the studies included in this review often did not report sufficient details (on cost outcomes, on implementation strategies, on fidelity, on power calculations). We were unable to draw firm conclusions regarding the cost-effectiveness of different strategies - thus we propose the need for more health economic research. Similarly, implementation strategies were often poorly described in most of the included papers, a common finding in implementation trials⁶⁸, making it hard for reviewers to clearly identify and characterise effective elements of strategies. Finally, several sources of variation may have impacted on patient-level outcomes, such as different populations from different countries, variables that we were not able to include in the meta-regression. All studies with outcomes on patient alcohol consumption were pooled and showed no effect. It is important to bear in mind that this does not imply that implementation strategies cannot change alcohol consumption; rather, it suggests that it is important to purposefully select implementation strategies, as they may differ in effectiveness. For instance, combining patient and professional oriented strategies appears to be more effective compared to a professional oriented single strategy. Due to a lack of studies with common elements within the main categories of EPOC and a high heterogeneity of implementation strategies, we could only draw conclusions based on the main categories of EPOC's taxonomy of interventions (professional, organisational and patient oriented implementation strategies). Pooling of implementation strategy elements would have provided more precise information.

In conclusion, in order to increase SBI delivery and decrease patients' alcohol consumption, this study has shown that implementation should ideally include a combination of patient, professional and organisational oriented implementation strategies and involvement of other staff working with physicians. To explain the lack of effect on alcohol consumption when SBI delivery was increased, the fidelity of SBI delivery to detect effects in patient's alcohol consumption should be investigated. Furthermore, evidence for new and innovative combinations of multiple implementation approaches to increase alcohol focused SBI uptake in PHC, is required.

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4

Chapter 4

*Implementing training and support,
financial reimbursement, and referral
to an internet-based brief advice programme
to improve the early identification of hazardous and
harmful alcohol consumption in primary care (ODHIN):
study protocol for a cluster randomised factorial trial*

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Abstract

Background: The European level of alcohol consumption, and the subsequent burden of disease, is high compared to the rest of the world. While screening and brief interventions in primary healthcare are cost-effective, in most countries they have hardly been implemented in routine primary healthcare. In this study, we aim to examine the effectiveness and efficiency of three implementation interventions that have been chosen to address key barriers for improvement: training and support to address lack of knowledge and motivation in healthcare providers; financial reimbursement to compensate the time investment; and internet-based counselling to reduce workload for primary care providers.

Methods/design: In a cluster randomised factorial trial, data from Catalan, English, Netherlands, Polish, and Swedish primary healthcare units will be collected on screening and brief advice rates for hazardous and harmful alcohol consumption. The three implementation strategies will be provided separately and in combination in a total of seven intervention groups and compared with a treatment as usual control group. Screening and brief intervention activities will be measured at baseline, during 12 weeks and after six months. Process measures include health professionals' role security and therapeutic commitment of the participating providers (SAAPPQ questionnaire).

A total of 120 primary healthcare units will be included, equally distributed over the five countries. Both intention to treat and per protocol analyses are planned to determine intervention effectiveness, using random coefficient regression modelling.

Discussion: Effective interventions to implement screening and brief interventions for hazardous alcohol use are urgently required. This international multi-centre trial will provide evidence to guide decision makers.

Background

The European Union (EU) has the highest alcohol consumption of the world: in 2009, the average adult (aged 15+ years) alcohol consumption in the EU was 12.5 litres of pure alcohol.¹ A review showed that consumption above 20 to 30 grams of alcohol a day (two to three glasses of wine) increases an individual's risks of mortality and morbidity.^{2,3} However, people often overestimate the positive health effects of alcohol; in fact, only small amounts of alcohol have positive effects on health.^{2,3}

Alcohol consumption is the third world leading cause of diseases and premature death.¹ The costs related to alcohol are €125bn a year for health, welfare, employment, and criminal justice sectors as a consequence of alcohol-attributable disease, injury, and violence.⁴ Therefore, individuals and society would benefit from effective preventive measures with respect to morbidity and mortality and social costs.

There is considerable evidence showing that early identification of hazardous and harmful alcohol consumption result in reduced alcohol consumption and improved health outcomes. Primary healthcare (PHC) is the primary point of contact for many people seeking healthcare. In this setting, screening⁵ and brief intervention programs have proven to be effective in reducing alcohol consumption⁶⁻¹⁰, with a mean reduction of 38 grams of alcohol per week (three to four glasses of wine).¹⁰ Although the evidence is still inconsistent about positive effects of nurse-led interventions^{11,12}, generally screening and brief interventions are provided by healthcare workers such as GPs, nurses, or psychologists.¹⁰ The number needed to treat (NNT) in offering screening and brief interventions is eight (for every eight people treated one will change their behaviour)¹³, which is relatively low compared to smoking cessation, which has a NNT of around 35 or higher.¹⁴ Despite the evidence for efficacy and cost-efficacy of screening and brief interventions in PHC, these interventions are rarely implemented in routine practice.¹⁵ Commonly, less than 10% of the population at risk are identified, and less than 5% of those who could benefit are offered screening and brief interventions in PHC settings.¹⁵

Some of the reasons for this gap are identified and can be categorised in three main domains. First, evidence suggests there is substantial lack of knowledge among general practitioners (GPs).^{5,16} A survey across 13 countries found that one-third of all GPs reported never receiving alcohol-related education, 23% reported less than four hours, and 37% reported more than seven hours of alcohol-related education ever.¹⁷ A recent update from England has shown that 52% of the United Kingdom's surveyed GPs indicated that they had received less than four hours of post-graduate training, continuing medical education, or clinical supervision on alcohol and alcohol related problems.¹⁸ Furthermore a lack of role security and therapeutic commitment has been identified.¹⁹

Secondly, lack of adequate resources and support are identified as important barriers.^{16,20} Financial reimbursement could be important measures to overcome this

barrier, but as far as we know, there have been no randomised controlled trials conducted investigating the impact of reimbursement for alcohol screening and brief interventions in the PHC setting.

The third important barrier relates to time constraints in terms of perceived workload and work pressure for screening and brief intervention activities.⁵ In PHC, trained nurses are increasingly involved in preventive care activities and in the management of chronic ill patients due to the increased workload of GPs. It has shown that they provide safe and effective care.²¹ This study focuses on all healthcare professionals working at primary healthcare units (PHCUs).

Although previous implementation studies^{22,23} have tried to increase screening and brief interventions in primary healthcare, the gap between scientific knowledge and everyday clinical practice remains.²⁴ With regard to the first category of barriers of knowledge and attitude, earlier studies found that training and support could make GPs even less secure in their work with drinkers, when the training and support does not address prior GP's attitude in the training and support.^{15,19} In the ODHIN study, we will tailor our implementation strategy to the primary healthcare worker's prior attitude. With regard to the second category, lack of resources, there are mixed results of evidence of finance systems to change provider behaviour.^{25,26} There is limited evidence that finance systems can change provider behaviour of screening and brief interventions of alcohol.¹⁵ Still, financial incentives for smoking cessation interventions have shown a significant positive outcome on increases in referral to tobacco cessation services²⁷, and suggest financial support for alcohol interventions might be effective. In the third category, workload and work pressure, we suggest e-health interventions might be of benefit. E-self help interventions without therapist support are available both in brief and more extended formats and have shown to be effective in reduction of alcohol consumption.²⁸ Additionally, internet interventions with therapist support focused on depression and anxiety were found to have larger effect sizes compared to internet interventions without therapist support²⁹, but has not yet been tested for alcohol internet interventions. These e-health interventions might be helpful to reduce workload of healthcare professionals after identification of patients at risk as well as availability for patients 24 h a day. Therefore, it is of interest to test if primary healthcare workers' referral to internet-based brief interventions, hereafter termed e-BI, could be time-saving for healthcare professionals and consequently might raise primary care worker's intervention activity.

It is of significant public health interest to explore, and optimise, effective implementation strategies to improve PHC activities in screening and brief interventions for hazardous and harmful alcohol consumption. In the current study, we evaluate the effect of three strategies, each aimed to tackle one of the above reported barriers, singly or in combination, in order to overcome the gap between knowledge and daily practice.

Aim and objectives

Our aim is to study the effectiveness of training and support (T&S), financial reimbursement, and internet based brief interventions (e-BI), targeted singly or in combination to primary healthcare units, on screening and brief intervention activities, compared to treatment as usual.

The following hypotheses will be tested in the study:

1. Provision of training and support to primary healthcare providers will increase use of preventive screening and brief interventions compared to a care as usual control group.
2. Financial reimbursement to primary healthcare providers as a pay-for-performance of brief alcohol interventions will increase screening and brief intervention rates compared to care as usual.
3. Providing resources, i.e., offering referral possibility to an internet-based method of delivering brief intervention, will increase screening and brief intervention rates compared to care as usual.
4. The combination of training and support, financial reimbursement, and e-BI will be more effective in increasing screening and brief intervention rates compared to single-focused implementation strategies.

Methods***Design***

Our study is designed as a cluster randomised factorial trial. Data from PHCUs in Catalonia, England, the Netherlands, Poland, and Sweden will be combined to examine the effect of three different implementation strategies singly or in combination on screening and brief advice rates for hazardous and harmful alcohol consumption compared with care as usual (controls). In all countries, the complete trial will be conducted between August 2012 and December 2013.

Participants

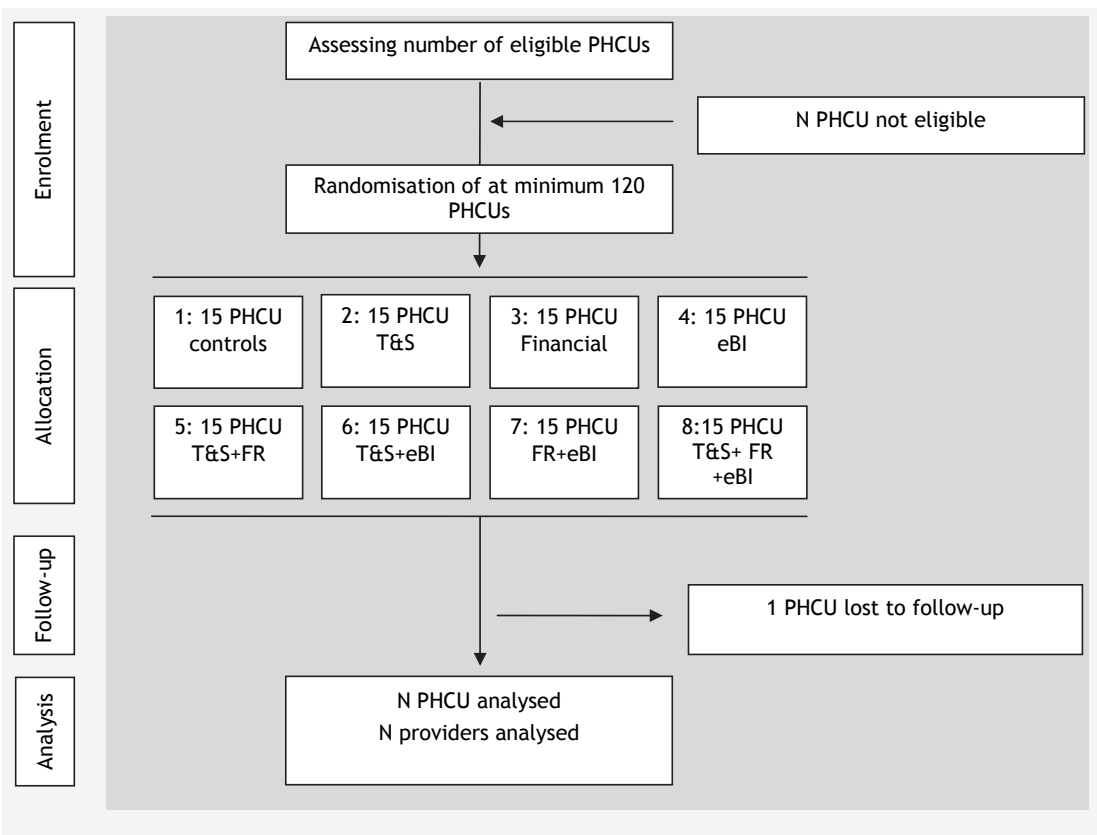
PHCUs with approximately 5,000 to 20,000 registered patients will be the unit of randomisation and implementation. In Poland, because practitioners normally operate as single-handed entities working with other practitioners in one building, three practitioners and their staff working in one building will be the unit of randomisation. PHCUs who agree to participate in the study are volunteers that will be drawn from administrative or academic registries of PHCU at national or regional levels. PHCUs that have current ongoing alcohol-related projects that have a focus on screening and brief interventions, involve GPs and/or nurses, and include one of the ODHIN implementation strategies, will be excluded.

Besides fully-trained GPs, nurses or practice assistants with a permanent appointment working in the PHCU and involved in medical and/or preventive care are also eligible, because they also have skills to assist in screening and brief interventions.

12,30,31

At the start of the study, all eligible providers within the PHCU will be identified by the research team. Participating providers are those eligible providers who agree to participate in the trial. Before baseline measurement, the participating providers have to sign up for the study, allowing PHCU with a high number of staff to include only a selection of staff. Staff not able to attend this meeting but willing to participate will be informed by the contact person in the PHCU. These providers will also sign an informed consent for their participation. In the Netherlands, England, Poland and Sweden, PHCU will receive a trial fee. The trial flow chart is shown in Figure 1.

Figure 1. Trial flow chart



Implementation strategies

The implementation period will last twelve weeks, with the start date for each country between November 2012 and March 2013. The start date of the implementation period for each PHCU will be staggered. Implementation strategies are outlined in detail in

Table 1. All groups will receive the same input as controls but with additional components added. These strategies are about to be tested singly or in combination:

1. Control group, treatment as usual
2. T&S
3. Financial reimbursement
4. e-BI
5. T&S and financial reimbursement
6. T&S and e-BI
7. Financial reimbursement and e-BI
8. T&S, financial reimbursement, and e-BI

Table 1. Outline of intervention groups with three different implementation strategies

1. Control Group—treatment as usual: The control group will receive a package, either hand-delivered or by post, containing a summary card of the national guideline recommendation for screening and brief advice for hazardous and harmful alcohol consumption, without demonstration. In Poland, where no national guidelines exist, the summary card will be adapted from the PHEPA guidelines for the purposes of this trial³³. No further instructions will be given.

2. Training and support: Countries differ largely with regard to usual T&S and other educational training of primary care staff. To maximise comparability, a set of minimal and maximal criteria have been established, in which each country specific T&S package should fit.

In addition to receiving the same package as the control group, the T&S group will be offered two initial 1 to 2 hours face-to-face educational trainings, and one (10 to 30 minutes) telephone support call to the lead PHCU contact person during the twelve week implementation period. If necessary, one additional face-to-face training of 1 to 2 hours duration will be offered. The time intervals between the initial training, the telephone call, and the additional optional training will be, on average, two weeks. The training addresses knowledge, skills, attitudes, and perceived barriers and facilitators in implementing screening and brief advice, combining theory and practical exercises. The location of the educational training will vary from country to country and include in-house meetings at the PHCU or within clusters of PHCUs. The trainers will include peer trainers, members of the research team, accredited teachers, or addiction consultants. Each country will use an adapted existing country-based T&S package. In the case of Poland, the T&S package will be based on the PHEPA training program.

3. Financial incentives: In addition to receiving the same package as the control group, financial incentive groups will be paid for their registered screening and brief intervention activities. Payment depends on normal country specific fees and rates for financial incentives for clinical preventive activities.

4. e-BI: In addition to receiving the same package as the control group, the e-BI group will be asked to refer identified at risk patients with an e-leaflet with unique log in codes to an approved e-BI specific package, which will be country specific, or, for Poland based on the WHO e-SBI program. The website should include the following: Log-in facility to allow monitoring of the patient (*i.e.*, patient actually log-in); suitable brief screening tool with ability to calculate score and give feedback (*i.e.*, brief intervention); appropriate information on sensible drinking guidelines; information on impact of alcohol on health and wellbeing; and a drink diary facility. Furthermore, the website could offer reminder facilities for follow-up activity.

5. T&S and financial incentives: The T&S and financial incentive group will receive the package, T&S, and the financial incentives as described above.

6. T&S and e-BI: The T&S and e-BI group will receive the package, T&S as above, and will be asked to refer identified at risk patients to e-BI as above.

7. Financial incentives and e-BI: The financial incentive and e-BI group will receive the package and will be asked to refer identified at risk patients to e-BI as above. They will be paid for screening, referral performance to e-BI, and brief advice if actually delivered, with the system of pay as above.

8. T&S, financial incentive and e-BI: The T&S, financial incentive and e-BI group will receive the package and T&S as above. They will be asked to refer identified at risk patients to e-BI as above. They will be paid for screening, brief advice activities, and referral performance to e-BI, with the system of pay as above.

A graphical depiction of the study is depicted in Additional file 1.

An introductory meeting (first briefing) will be held in all PHCUs that agree to participate in the study, describing the study's purpose and the four-week baseline data collection, which will follow the introductory meeting. After the baseline data collection, all PHCUs will receive a second briefing within one month, either face to face or by telephone, tailor-made to the study group to which they are allocated.

Outcomes

Primary outcomes: screening and brief advice rates

PHCUs will be asked to screen all patients aged 18 years and over who attended the PHCU. These patients are defined as eligible patients.

Patients will be screened for hazardous and harmful alcohol consumption with AUDIT-C.³² Screen positives, or at risk patients, are defined as those who scored ≥ 5 for men or ≥ 4 for women on AUDIT-C. Participating staff that have signed up to the study will be asked to deliver brief alcohol advice of 5 to 15 min duration to at-risk patients, with the length and format of the brief advice based on country-specific guidelines or, for Poland where national guidelines are lacking, the European guidelines developed by PHEPA.³³ Providers of PHCUs allocated to e-BI activity will be asked to refer patients to a computerised brief advice program, considered equivalent to providing brief advice. Besides counting referral rate to e-BI, actual e-BI log-in rates of patients will be collected.

Screening and brief advice will be measured at five timepoints: during the four-week baseline period, the three consecutive four-week blocks during the twelve week implementation period; and, the four-week follow-up period, which will occur during the seventh month after the end of the twelve-week implementation period using paper tally sheets, with the exception of Catalonia who will use their electronic patient records. The tally sheets include AUDIT-C scores (i.e., identification of at risk patients) with additional table to indicate the type of brief advice that was delivered to the patients at risk. Gender and age of patients will be recorded as well as the name and profession of the provider.

The screening rate will be calculated as the number of completed screens divided by the total number of consultations of all patients eligible for screening (as defined above) per participating provider times 100. The brief advice rate will be calculated as the number of BIs delivered (received oral brief advice, and/or were given an advice leaflet, and/or were referred to the e-BI program, and/or were referred to another provider in or outside the practice), divided by the total number of screen positives per participating provider times 100. Information will also be collected on the number of screen negatives who received brief advice.

Screening and brief advice rates will be calculated at two levels: at an aggregate PHCU level for all participating providers in the PHCU; and, at an individual provider level for each participating and actively participating providers.

Participating providers are defined as those who attended the first briefing, or who were identified as joining the study by the contact person of the PHCU at the first briefing. Actively participating providers are defined as those participating providers who completed at least one tally sheet or computerised record during one of the measurement periods.

Secondary outcomes: role security and therapeutic commitment

Role security and therapeutic commitment of the participating providers will be measured by the short version of the Alcohol and Alcohol Problems Perception questionnaire (SAAPPQ) [34] at three time points: at or immediately after the first introduction meeting, at the end of the 12-week implementation period, and during the end of the four-week follow-up period. All participating providers who have signed an informed consent will be asked to complete the SAAPPQ at each of the three time points. The responses will be summed within the two scales of role security and therapeutic commitment.

Individual missing values for any of the items in a domain will be assigned the mean value of the remaining items of the domain before summation.

Randomisation and blinding

Randomisation will take place after formal agreement of the PHCU to take part in the trial. The PHCU will be randomly allocated to one of eight groups by the European coordinating centre, using computerised randomisation stratifying by country, ensuring 15 PHCUs per Group (three per country). Although the PHCUs will be randomly allocated before the baseline measurement, the research team in each of the countries and the PHCU only are informed of the allocation after collection of the baseline measurement to avoid bias as a result of group allocation.

For the remainder of the study period, the PHCU and investigators will not be blind to group allocation.

Sample size

It is estimated that 56 PHCUs (seven per eight allocation groups) with a minimum of 1,000 eligible patients per month would be needed for a 80% chance of detecting an increase in screening rates from 8% to 12% ($ICC = 0.029$) and that 120 PHCUs (15 per eight allocation groups) would be needed for a 80% chance of detecting an increase in brief advice rates from 4% to 6% ($ICC = 0.029$) ($\alpha = 5\%$). As country is used as stratification criteria each country has to include a minimum of 24 PHCUs. These conservative estimates are based on published evidence of screening and advice rates.
22,23

Statistical methods

Because of the hierarchical structure of the data (individual providers nested within PHCU nested within country), we will perform multilevel analyses of the screening and advice rates to examine the effect of the implementation strategies in comparison with the controls. The intention to treat analyses will include all participating providers (see above). Per protocol analyses will include only actively participating providers (see above). In all the analyses, we will use exposure to the implementation strategy as covariate. Exposure is defined as positive if the providers meet the following criteria: financial—the PHCU received the financial reimbursement; e-BI—the provider handed out at least one referral card; and T&S—the provider attended the two face-to-face educational meetings. If these criteria will not be met, the exposure will be defined as negative.

Analyses will be performed in SAS V9.2 and based on mixed effects model (PROC GLIMMIX and PROC MIXED). We will use a random intercept model with fixed variables.

Discussion

By conducting this trial, we are trying to address the well-known implementation gap (evidence to practice) of screening and brief interventions for hazardous and harmful alcohol consumption in PHC. For example, researchers rarely have been in a position to actively compare a number of incentive-based strategies. With this trial, we aim to assist in building a knowledge base, on which policy could be based on.

We are aware of some strengths and limitations of this trial. This trial is approached pragmatically. In other words, each of the five countries differs slightly in the implementation strategy contents. For example, countries will differ in their distribution of research fees, amount of financial reimbursements, and deliverers of training and support strategies. The research team explicitly determined this pragmatic approach, because they considered this approach being most valuable for country policy makers. Albeit, in terms of research, this is less powerful because there are small variations in implementation strategies per country.








The five participating countries are different in their organisation of primary care and have different drinking patterns. This creates opportunities to conduct across country analyses and relate different implementation rate outcomes to cultural and organisational differences. These results can consequently be applicable through Europe and other similar Western countries. In the future, if our implementation strategies result in improved screening and brief intervention rates, other countries with comparable primary care systems could use these strategies to improve the prevention of hazardous and harmful alcohol consumption in their country.

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Additional file 1: Graphical depiction of ODHIN study

-  30 min introduction to study (*First meeting*)
-  SAAPPQ measurement 1) before baseline; 2) after implementation period; 3) follow-up
-  collecting tally sheets of SBI activity at 1)baseline; 2)month 1 implementation; 3) month 2 implementation; 4) month 3 implementation; 5) follow-up
-  15 min second meeting introduction to study arms (within control and financial reimbursement only arm- just simple phone call)
-  Training & Support
-  Financial reimbursement
-  e-BI

Time schedule	Period	Control group	T&S	Financial	e-BI	T&S+ Financial	T&S+e-BI	Financial +e-BI	T&S+ Financial +e-BI
Baseline: 1 month	September 2012 - February 2013	1 a b	1 a b	1 a b	1 a b	1 a b	1 a b	1 a b	1 a b
Randomisation									
1 month	October 2012 - March 2013	2 a b	2 a b	2 a b	2 a b	2 a b	2 a b	2 a b	2 a b
Implementation period: 3 months	November 2012 - June 2013	a b	a b	a b	a b	a b	a b	a b	a b
Follow-up: 6 months after implementation finished	July 2012- December 2013	a b	a b	a b	a b	a b	a b	a b	a b



Procedure activities



Measures

5

Chapter 5

Professional's attitudes do not influence screening and brief interventions rates for hazardous and harmful drinkers: Results from the ODHIN Study

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Abstract

Aims: To determine the relation between existing levels of alcohol screening and brief intervention rates in five European countries and role security and therapeutic commitment by the participating primary healthcare professionals.

Methods: Health care professionals consisting of, 409GPs, 282 nurses and 55 other staff including psychologists, social workers and nurse aids from 120 primary health care centres participated in a cross-sectional 4-week survey. The participants registered all screening and brief intervention activities as part of their normal routine. The participants also completed the Shortened Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ), which measure role security and therapeutic commitment.

Results: The only significant but small relationship was found between role security and screening rate in a multilevel logistic regression analysis adjusted for occupation of the provider, number of eligible patients and the random effects of countries and primary health care units (PHCU). No significant relationship was found between role security and brief intervention rate nor between therapeutic commitment and screening rate/brief intervention rate. The proportion of patients screened varied across countries between 2 and 10%.

Conclusion: The findings show that the studied factors (role security and therapeutic commitment) are not of great importance for alcohol screening and BI rates. Given the fact that screening and brief intervention implementation rate has not changed much in the last decade in spite of increased policy emphasis, training initiatives and more research being published, this raises a question about what else is needed to enhance implementation.

Introduction

Despite strong evidence for the effectiveness and cost-effectiveness of screening and brief alcohol intervention (SBI) in primary health care settings (PHC)¹⁻⁵ implementation is still considered to be far too low in relation to the proportion of patients with risky and heavy drinking seen in PHC.⁶⁻⁸ In a review of effectiveness of strategies to implement SBI in primary health care it was seen that implementations effectiveness (material utilization, screening and BI rates) generally increased with the intensity of the implementation effort. Nevertheless, in all reviewed studies, the overall effect was rather modest.⁹

A numbers of barriers such as lack of time and resources as well as inadequate support hamper SBI in PHC.^{5,7,9} Insufficient knowledge and skills by staff have been suggested as important barriers in several reports, including negative attitudes among practitioners not agreeing that SBI is a legitimate part of their work.^{6,7}

In order to overcome some of these barriers a number of implementation projects have been conducted during the last decade. These studies mainly focus on professional education and organizational barriers, but do not address staff attitudes. Studies that offered tailored strategies, including work on attitudes did not seem to be successful in changing negative attitudes. More research into PHC practitioner's role security, therapeutic commitment and motivation for BI implementation has been suggested in order to gain more knowledge on how to design effective implementation strategies.^{9,10}

There is some evidence that with more positive role security and therapeutic commitment providers are managing more patients with risky and heavy drinking.^{11,12} In a recent cross-sectional survey of 2345 GPs in eight European countries a high level of role security was expressed but less therapeutic commitment.¹³ Providers with higher values of role security and therapeutic commitment reported managing a higher number of patients with risky and heavy alcohol use.

One study in primary care with a tailored multi-faceted programme to increase role security and therapeutic commitment in the Netherlands showed an increase of the GPs therapeutic commitment but not role security, one year after the programme was implemented.¹⁴ Screening and BI rate did not improve, probably due to no change in role security and therapeutic commitment.^{14,15} A similar study in the US resulted in both improved role security and therapeutic commitment but again no improvement on screening and BI rates was observed.¹⁶

Underlining, however, the importance of role security and therapeutic commitment, in an overview by Anderson in 2009, it was found that although training and support has shown to have some effects on the implementation of BI, the absence of means of increasing role security and therapeutic commitment of participants in such educational programmes might diminish the effect and in certain cases could even be

harmful to those who have low levels of role security and therapeutic commitment at baseline.⁶

Survey data of GPs in the UK, both in 1999 and 2009, showed high levels of role security but lack of therapeutic commitment. The reason given for the lack of progress was practical limitations for preventive service such as lack of time and support rather than attitudinal.¹⁷

In summary, the evidence so far is not conclusive regarding the relation between role security and therapeutic commitment among primary health care professionals and SBI rates. Furthermore, the relationship has mostly so far been examined among GPs using cross sectional self-reporting of number of patients managed. It is important from a public health perspective to investigate and enhance effective implementation strategies to increase activities in SBI for hazardous and harmful alcohol consumption in primary health care). The present study reports results of a 4-week survey performed before the implementation of the optimizing delivery of health care intervention (ODHIN) study and analysis the existing levels of SBI rates in five European countries in relation to role security and therapeutic commitment by the participating primary healthcare professionals.

Methods

The ODHIN study is a cluster randomized factorial trial undertaken in 120 primary health care units (PHCUs) in Catalonia, UK, the Netherlands, Poland and Sweden.¹⁸ To assess the relationship between role security and therapeutic commitment and SBI behaviour we used data collected at baseline before the start of the main implementation study.

Study setting and participants

Each of the 120 participating PHCUs had approximately 5000-20,000 registered patients. In Poland, since practitioners normally operate as single-handed entities working with other practitioners in one building, two or three practitioners and their staff working in one building were considered as one PHCU. Those units who agreed to participate in the study were volunteers drawn from administrative or academic registries of PHCU at national or regional levels in the participating countries.

Eligible providers in each unit included any fully trained GPs, nurses, social workers, psychologists or practice assistants with a non temporary employment contract involved in medical and/or preventive care. In Poland only GPs participated in the study. At the start of the study all eligible providers within the PHCU were identified by the research team and the study was explained to them in an introductory meeting. In the introductory meeting interested providers were given a short overview of the study and asked to sign an informed consent if interested in participating. An option was given to sign the consent form within a week. Interested providers not able to participate in the

introductory meeting were given a personal introduction by a lead contact person appointed by the PHCU for the trial.

A total of 746 individual providers agreed to take part and signed an informed consent form; 409 GP's, 282 nurses and 55 'other staff' entailing psychologist, social workers and nurse aids.

In some countries, the PHCU received a basic research fee for participating in the ODHIN study. In The Netherlands the fee to each PHCU was €250, in Poland €500-750 and in Sweden €2500. In Catalonia and UK no basic research fee was given.

Measures

Screening and brief intervention

During the four-week measurement period, the participating providers were asked to manage hazardous and harmful drinking patients as close as possible to their usual routines. Thus, each provider had to decide when a screening was appropriate to perform during a consultation and then register each screening and brief intervention activity on a special tally sheet designed for the study, with the exception of Catalonia who used their electronic patient records. The tally sheets included AUDIT-C scores (i.e. identification of at risk patients) with additional boxes to indicate the type of brief advice that was delivered to the patients at risk.

Patients were to be screened for hazardous or harmful alcohol consumption with the AUDIT-C questions. Screen positives were defined in Catalonia and UK as men and women who scored ≥ 5 on AUDIT-C, and in Poland, The Netherlands and Sweden as men who scored ≥ 5 and women who scored ≥ 4 on AUDIT-C as per country definitions of hazardous or harmful drinking. During the baseline measurement period, no specific instructions were given concerning the length and content of the brief intervention but if any advice was given (including only handing over a leaflet) this was to be recorded as a brief intervention.

Screening and brief advice rates

Screening and brief advice were measured on paper tally sheets. The screening rate was calculated as the number of patients screened divided by the number of patients eligible for screening in the time frame, i.e. all visit to the PHCU being 18 years of age or older per participating provider times 100. The brief advice rate was calculated as the number of screen positive patients that received oral brief advice, or were referred to another provider in or outside the practice for brief advice, divided by the total number of screen positive patients per participating provider times 100. Information was also collected on the number of screen negatives who received brief advice.

Role security and therapeutic commitment

Role security and therapeutic commitment of the participating providers in working with patients with alcohol use disorders were measured by the short version of the Alcohol and Alcohol Problems Perception questionnaire (SAAPPQ) (Anderson, 1985; Anderson and Clement, 1987).^{19,20} Respondents were informed that the questions are designed to explore the attitudes of staff working with people with alcohol use disorders. The term alcohol use disorders was not defined. The questionnaire comprised 10 statements, which addressed five subscales: (a) role adequacy (b) role legitimacy; (c) motivation; (d) task specific self-esteem; and (e) work satisfaction. Responses to the statements were scored from 1 (strongly disagree) to 7 (strongly agree). Scores on the subscales 'role adequacy' and 'role legitimacy' were merged to form an index of 'role security', as described by Anderson and Clement (1987)²⁰, originally derived from the full Alcohol and Alcohol Problems Perception Questionnaire (AAPPQ) (Cartwright, 1980)²¹ with a total score ranging from 4 to 28. The subscales relating to 'self-esteem', 'motivation' and 'work satisfaction' were merged to an index of 'therapeutic commitment' with a score ranging from 6 to 42 as described by Anderson and Clement (1987)²⁰, originally derived from the full AAPPQ (Cartwright, 1980).²¹ Individual missing values for any of the items in a domain were assigned the mean value of the remaining items of the domain before summation.

Role security measures role adequacy, for example 'I feel I can appropriately advise my patients about drinking and its effects'; and role legitimacy, for example, 'I feel I have the right to ask patients questions about their drinking when necessary'. Role insecurity is expressed at the emotional level as therapeutic commitment which measures motivation, for example 'pessimism is the most realistic attitude to take toward drinkers'; task specific self-esteem, for example 'all in all I am inclined to feel I am a failure with drinkers'; and work satisfaction, for example 'in general, it is rewarding to work with drinkers'.

The SAAPPQ was derived from the full AAPPQ, which had been developed and validated as part of the Maudsley Alcohol Pilot Project (MAPP) set up to design a comprehensive community response to alcohol problems (Shaw et al., 1978).¹¹ Scores on the indices of role security and therapeutic commitment were found to be predictive of the involvement of primary care providers (including general practitioners and social workers) in managing alcohol problems. Providers who were role insecure were also therapeutically uncommitted. By providing training and support in their role, providers increased their experience and effectiveness in managing alcohol problems, reflected through increased role security and therapeutic commitment.

Practice and provider characteristics

Besides the SAAPPQ questionnaire, the survey also included questions regarding practice and provider characteristics. These concerned age, sex and profession of the

individual provider. Profession were divided into GP, Nurse or other staff including psychologist, social worker or nurse aids.

Analysis

The primary outcomes of the multilevel analysis (individuals nested within PHCU nested within countries) were screening and brief advice rates. The distribution of screening rate per provider was highly positive skewed and a logarithmic transformation did not help to normalize the distribution, therefore screening rate was dichotomized at the median and analysed by logistic regression (Table 1).

Table 1. Median and Interquartile range of screening and BI rate in the five participating countries

Country	Screening		Brief Interventions	
	Sample	Median Screening rate (IQR)	Sample	Median BI rate (IQR)
Catalonia	239	4.0% (0.9-9.6%)	110	66.7% (0.0-100.0%)
England	122	2.4% (0.3-6.9%)	90	100.0% (87.1-100.0%)
Netherlands	153	2.7% (0.6-13.5%)	109	100.0% (50.0-100.0%)
Poland	66	0.0% (0.0-1.4%)	25	100.0% (100.0-100.0%)
Sweden	166	6.5% (1.4-21.1%)	109	100.0% (42.2-100.0%)
Total	746	3.1% (1.0-11.2%)	443	100.0% (50.0-100.0%)

The distribution of BI rate per provider was skewed in more than one direction and therefore it was categorized into three categories; low, middle and high BI rate and analysed by ordered logistic regression with cut points Low: BI-rate ≤ 0.4 ; Middle: BI-rate >0.4 and <1 ; High: BI-rate = 1 (Table 1). The distribution of BI rate was multimodal with a low peak at 0 with 19% of the observations ($85/443 = 19\%$) and a ceiling effect at 1 with 55% of the observations ($244/443 = 55\%$). A cut point of 0.4 was therefore chosen so approximately half of the observations strictly lower than 1 were between 0 and 0.4 ($102/443 = 23\%$), and half between 0.4 and 1 ($97/443 = 22\%$).

The analysis of SBI rate in relation to role security and therapeutic commitment was performed with a multilevel regression analysis taking into account the hierarchical structure of the data (individuals nested within PHCU nested within countries) with random intercept in order to examine the association of screening and BI rate with role security and therapeutic commitment adjusted for occupation of the provider, number of eligible patients (for the analysis of screening rate) and numbers screened (for the analysis of BI rate).

Effect modification analysis was performed for possible interaction between role security and therapeutic commitment with occupation by adding the appropriate interaction term to the adjusted multilevel regression model. Multilevel logistic regression models adjusted for the random effects of PHCU and country were then calculated separately by occupation. Effect modification analysis to assess country-by-occupation interaction was performed by adding a random slope effect for occupation at the country level to the multilevel regression model. Multilevel logistic regression

models adjusted for the random effect of PHCU were then calculated separately by country for GPs, nurses and ‘other staff’.

The statistical analysis was performed using STATA 13.0. A level of 5% was considered as statistically significant.

Results

Study population

A total of 746 individual providers from 120 PHCU signed an informed: 409 GPs, 282 nurses and 55 ‘other staff’ entailing psychologist, social workers and nurse aids. The number of eligible providers per practice averaged 6.2, which ranged from 2.75 to 9.96 across the countries. Most participants managed to screen at least one patient but 160 providers (21.4%) did not record screening a single patient during the 4-week survey period. The proportion of non-active providers was highest for GP’s (28.9%) (Table 2). The number of registered patients averaged 10,000 across the 120 practices, with averaged 1500 eligible consultations per practice during the four-week baseline period. Thus the included PHCUs take care for a population of 1.2 million people, and saw about 179,954 eligible patients during the four-week period.

Table 2. Participating providers in each country divided into staff categories and active and non-active participation (*Having screened at least one patient during the 4-week measurement period.*)

Country	GP		Nurse		Other		Total	
	Active	Non-active	Active	Non-active	Active	Non-active	Active	Non-active
Catalonia	105	20	105	8	0	1	210	29
England	52	20	33	4	10	3	95	27
Netherlands	64	24	41	3	15	6	120	33
Poland	31	35	0	0	0	0	31	35
Sweden	39	19	72	16	19	1	130	36
Total	291	118	251	31	44	11	586	160

Screening and brief intervention rates

A total of 9609 patients (5.3%) were screened. The mean screening rate ranged from 1.7% in Poland to 9.8% in Sweden (Table 3).

A total of 1626 (16.9%) patients had a positive AUDIT-C score ranging from 4.7% of the screened patients in Catalonia to 43.4% in UK (Table 4). Of these positive screened patients 1202 (73.9%) were given a brief intervention. The proportion of screened positive receiving brief intervention varied from 59.2% in Catalonia to 94.2% in Poland.

Table 3. Characteristics of numbers of screened patients in relation to numbers of eligible patients and numbers of providers for each participating country

Country	Numbers of participating providers	Numbers of eligible patients	Numbers of patients screened	Proportion of patients screened ^a %
Catalonia	239	83327	5325	6.4
England	122	26104	1042	4.0
Netherlands	153	25366	1388	5.5
Poland	66	31615	527	1.7
Sweden	166	13542	1327	9.8
Total	746	179954	9609	5.3

^a Calculated as total numbers of patients screened divided with the total numbers of eligible patients for each country times 100.

Table 4. Screening rate, positive screening rate and brief intervention rate for each country

Country	Numbers screened positive	Proportion of patients screened positive %	Numbers receiving brief intervention	Proportion of patients with a positive screening receiving brief intervention
Catalonia	250	4.7	148	59.2
England	452	43.4	390	86.3
Netherlands	465	33.5	335	72.0
Poland	103	19.5	97	94.2
Sweden	356	26.9	232	65.2
Total	1626	16.9	1202	73.9

Role security and therapeutic commitment

On average the providers scored 21.00 (SD 3.51) on role security and 27.20 (SD 4.67) on therapeutic commitment, which could be regarded as providers felt secure and were therapeutically committed. GP's had a slightly higher role security than all other providers but the lowest therapeutic commitment; this was highest for the staff group 'others' (Table 5).

Table 5. Mean (SD) score for role security (RCB)^a and therapeutically commitment (TCB)^b divided into country and occupation

Country	GP mean (SD)		Nurses mean (SD)		Others mean (SD)		Total mean (SD)	
	RSB	TCB	RSB	TCB	RSB	TCB	RSB	TCB
Catalonia	20.31 (2.55)	27.30 (3.14)	18.85 (3.08)	26.65 (4.11)	-	-	19.62 (2.89)	26.98 (3.63)
England	22.35 (3.13)	27.39 (4.26)	20.41 (3.93)	28.54 (3.69)	20.06 (4.03)	28.64 (6.32)	21.52 (3.60)	27.87 (4.34)
Netherlands	20.93 (3.67)	25.05 (3.99)	19.64 (3.17)	25.75 (4.16)	17.52 (3.16)	25.94 (2.24)	20.08 (3.64)	25.38 (3.85)
Poland	21.71 (3.11)	25.04 (5.55)	-	-	-	-	21.71 (3.11)	25.04 (5.55)
Sweden	24.29 (2.28)	29.44 (5.25)	22.36 (3.18)	29.35 (5.36)	23.60 (3.28)	30.95 (5.73)	23.17 (3.03)	29.57 (5.36)
Total	21.59 (3.25)	26.76 (4.54)	20.29 (3.56)	27.61 (4.69)	20.36 (4.27)	28.36 (5.21)	21.00 (3.51)	27.20 (4.67)

^a Scale range from 0-28; ^b Scale range from 0-42

For all staff categories the Swedish staff had both the highest role security therapeutic commitment. In a series of separate bivariate correlation analysis between the screening and brief intervention rates and role security and therapeutic commitment in various staff categories and in each country, all correlations were small and non-significant except for the 'other staff' category (n=21) in the Netherlands (Spearman correlation between screening rate and role security, $r = 0.55$ ($P = 0.01$)).

Screening rate in relation to role security

The association between role security and screening rate was statistically significant (OR = 1.07, 95%-CI = [1.01, 1.14], $P = 0.02$) in the multilevel logistic regression analysis adjusted for occupation of the provider, number of eligible patients and the random effects of country and PHCU. In this analysis, the screening rate was significantly higher among nurses (OR = 8.31, 95%-CI = [4.99, 13.87], $P < 0.001$) and other staff (OR = 7.02, 95%-CI = [3.07, 16.03], $P < 0.001$) compared to GPs. The number of eligible patients of the individual provider did not influence the association between role security and the screening rate ($P = 0.06$).

There was a statistically significant effect modification between role security and occupation ($P = 0.04$). Therefore the multilevel analysis was stratified by occupation. Role security was related to a statistically significant increase in screening rate in function of role security among 'other staff' (OR = 1.39, 95%-CI = [1.06, 1.83], $P = 0.02$). The association between role security and screening rate was not statistically significant neither among GPs (OR = 1.06, 95%-CI = [0.96, 1.16], $P = 0.25$), nor among nurses (OR = 1.05, 95%-CI = [0.94, 1.16], $P = 0.39$).

There was a significant effect modification between country and occupation ($P = 0.003$). Therefore the multilevel analyses were stratified by occupation and country. There was a statistically significant difference between country among GPs ($P = 0.04$) where Poland and Sweden were the only countries with an odds ratio lower than 1 (NS), and among nurses ($P = 0.005$) where the Netherlands were the only countries with an odds ratio lower than 1 (NS). No effect modification was seen for the 'other staff' group ($P = 0.87$) where all countries had an odds ratio higher than 1 (NS).

Screening rate in relation to therapeutic commitment

The association between therapeutic commitment and screening rate was not statistically significant (OR = 1.02, 95%-CI = [0.98, 1.07], $P = 0.36$) in the multilevel logistic regression analysis adjusted for occupation of the provider, number of eligible patients and the random effects of country and PHCU. In this analysis, the screening rate was significantly higher among nurses (OR = 7.17, 95%-CI = [4.40, 11.68], $P < 0.001$) and other staff (OR = 5.70, 95%-CI = [2.56, 12.69], $P < 0.001$) compared to GPs. The number of eligible patients of the individual provider did influence the association

between therapeutic commitment and the screening rate (OR = 0.998, 95%-CI = [0.997, 1.000], $P = 0.04$).

There was an effect modification between therapeutic commitment and occupation ($P = 0.02$). Therefore the multilevel analysis was stratified by occupation. The odds ratio of screening rate in function of therapeutic commitment were not statistically significant but were higher than 1 both for GPs (OR = 1.04, 95%-CI = [0.97, 1.11], $P = 0.27$) and 'other staff' (OR = 1.15, 95%-CI = [0.93, 1.43], $P = 0.19$), and lower than 1 for nurses (OR = 0.94, 95%-CI = [0.87, 1.01], $P = 0.11$).

There was a significant effect modification between country and occupation ($P = 0.003$). Therefore the multilevel analyses were stratified by occupation and country. There was a statistically significant difference between country among GPs ($P = 0.04$) where Poland and UK were the only countries with an odds ratio lower than 1 (NS), and nurses ($P = 0.004$) where UK was the only country with an odds ratio higher than 1 (NS). No effect modification was seen for the 'other staff' category ($P = 0.82$) where all countries had an odds ratio higher than 1 (NS).

BI-rate in relation to role security

The association between role security and BI rate was not statistically significant (OR = 1.00, 95%-CI = [0.94, 1.06], $P = 0.93$) in the multilevel ordered logistic regression analysis adjusted for occupation of the provider, numbers screened and the random effects of country and PHCU. In this analysis, the BI rate was significantly different between nurses versus GPs (OR = 0.63, 95%-CI = [0.40, 1.00], $P = 0.048$), but was not significantly different between other staff versus GPs (OR = 0.61, 95%-CI = [0.28, 1.35], $P = 0.23$). The number of screened patients of the individual provider did influence the association between role security and the BI rate (OR = 0.99, 95%-CI = [0.98, 1.00], $P = 0.006$).

There was no evidence of effect modification between role security and occupation ($P = 0.87$), and neither between country and occupation ($P = 0.49$).

BI-rate in relation to therapeutic commitment

The association between therapeutic commitment and BI rate was not statistically significant (OR = 0.99, 95%-CI = [0.94, 1.04], $P = 0.74$) in the multilevel logistic regression analysis adjusted for occupation of the provider, screened numbers and the random effects of country and PHCU. In this analysis, the BI rate was significantly different between nurses versus GPs (OR = 0.63, 95%-CI = [0.41, 0.99], $P = 0.04$), but was not significantly different between other staff versus GPs (OR = 0.63, 95%-CI = [0.28, 1.39], $P = 0.25$). The number of screened patients of the individual provider did influence the association between therapeutic commitment and the BI rate (OR = 0.99, 95%-CI = [0.98, 1.00], $P = 0.007$). There was no evidence of effect modification

between therapeutic commitment and occupation ($P = 0.71$), and neither between country and occupation ($P = 0.49$).

Discussion

The aim of this study was to explore how role security and therapeutic commitment relates to actual SBI rates. However the only significant but weak association ($OR = 1.07$, $95\%-CI = [1.01, 1.14]$, $P = 0.02$) was found for role security and screening rate. The number of eligible patients of the individual provider did not influence the association between role security and the screening or BI rate.

A significant effect modification was seen between role security and occupation where the staff group 'other' was the only group that displayed a significant increase in screening rate with increasing role security. We found no significant relationship between therapeutic commitment and screening rate in the multilevel analysis. We neither found a significant relationship between role security and therapeutic commitment in relation to brief intervention rates.

The null-findings in our study concerning factors influencing screening and BI rate could on one hand suggest that other factors not studied might be more important (e.g. clinical priorities, management support or workload) or there could be a disjoint between practitioners' attitudes (as reflected in role security and therapeutic commitment) and their behaviour (as measured by screening and BI rate). We know that there can be a gap between intention and behaviour and that this might be explained by other factors at play that we did not measure such as other clinical priorities, management support or logistical challenges such as workload.

The null-findings could imply that the SAAPPQ is not a valid instrument for differentiating primary health care providers in their approach to screening and brief intervention for hazardous and harmful drinking. However, we do not think that this is the case. The SAAPPQ was derived by factor analysis²⁰ as a shortened survey version of the full AAPPQ, which had been developed and validated as part of the MAPP set up to design a comprehensive community response to alcohol problems.¹¹ The MAPP found that primary care providers (physicians and social workers) failed to recognize and respond to drinking problems because they felt anxieties about their role adequacy through not having the information and skills necessary to recognize and respond to drinkers; and, anxieties about their role legitimacy through being uncertain as to whether or how far drinking problems came within their responsibilities.¹¹ Primary care providers who experienced anxiety about these areas were defined on the basis of their responses to the AAPPQ as role insecure. Role insecurity was found to be caused by deficiencies either in primary health care providers' training or in their working situation. Role insecurity was expressed at the emotional level as therapeutic commitment, which measures motivation. Various versions of the AAPPQ were used by Cartwright and his colleagues but all contained within them a series of statements

about working with clients with alcohol-related problems with which the respondent was asked to indicate the extent of agreement on a seven point scale ranging from 'strongly agree' to 'strongly disagree'. For each scale a score was obtained by summing the individual item scores. Reliability and validity data relating to these scales have been reported.²¹⁻²⁴ By providing training and support in their role, providers in the MAPP increased their experience and effectiveness in managing alcohol problems, reflected through increased role security and therapeutic commitment.

The SAAPPQ has been widely used in different countries and cultures over sustained periods of time (UK, see Anderson¹⁹; Wilson et al.¹⁷; nine-country WHO study, see Anderson^{12,25}; six-country AMPHORA study, see Drummond et al.⁸ and the eight-country ODHIN study, see Anderson¹³. In all these studies, individual country and cross-country distributions of the role security and therapeutic commitment scales have been normally distributed with only relatively small variations in means and standard deviations between countries.

In cross-sectional surveys, scores on both role security and therapeutic commitment have been associated with differential provider behaviour. For example, cross-sectional surveys based on self-reported SBI outcome have found that both role security and therapeutic commitment are associated with an increased number of patients managed for hazardous drinking and alcohol problems.^{12,13} The associations may be explained by self-report data, with no external means of validation. Further, when surveys find a strong association between role security and therapeutic commitment with reported number of patients managed for heavy drinking, we do not know if it is role security and therapeutic commitment that predicts a higher number of patients reported as managed, or if it is that providers who report that they have managed a higher number of patients, score higher on role security and therapeutic commitment. However, similar to the present survey, when objective measurements of behaviour are used, the WHO Phase III survey failed to find role security and therapeutic commitment being associated with higher screening and BI rates.²⁵

Interestingly, and in support of the validity of the SAAPPQ scales in differentiating provider behaviour, the WHO Phase III study, found that, whereas training and support increased general practitioners' screening and brief intervention rates, it only did so for practitioners with initially high role security and therapeutic commitment. Surprisingly, the provision of training and support did not improve attitudes towards working with drinkers, and, for those who were already insecure in their role and who were therapeutically uncommitted, made attitudes worse, suggesting that training and support needs to be tailored to baseline attitudes. Also, in the WHO study, engagement in screening and brief intervention activity did not improve subsequent attitudes. For practitioners who were already insecure in their role, experience in brief interventions actually made their role security worse. In the ODHIN trial, we will be investigating the extent to which training and support and financial reimbursement change SAAPPQ

scores over time, and the extent to which changes in SBI activity over time are related to changes in SAAPPQ scores over time (Keurhorst et al., 2013).¹⁸

In general the participating providers in the current study displayed a fairly high level of role security but lower therapeutic commitment. In four of the countries (Spain, UK, Netherlands and Poland), a survey of a regional (Catalonia and UK) or national representative sample of general practitioners has also measured role security and therapeutic commitment (Anderson et al., 2014).¹³ The providers in the present study had higher role security (mean 21.00, SD 3.51) than the representative sample (mean 20.55, SD 2.94), anova, $F = 13.7$, $P < 0.001$; they also had higher therapeutic commitment (mean 27.20, SD 4.67) than the representative sample (mean 24.67, SD 4.74), anova, $F = 129.3$, $P < 0.001$. Comparing only the GPs in the present sample with the GPs in this national representative sample we found that they had higher role security (mean 21.59, SD 3.25) than the representative sample (mean 20.55, SD 2.94), anova, $F = 25.4$, $P < 0.001$. They also had higher therapeutic commitment (mean 26.76, SD 4.54) than the representative sample (mean 24.67, SD 4.74), anova, $F = 57.75$, $P < 0.001$.

A 10-year comparison between GP's attitudes and practices showed a stable high role security and relative low therapeutic commitment, especially low levels of motivation and job satisfaction, when working with either risky or heavy drinkers (18). From these findings it appears that increasing therapeutic commitment remains to be a great challenge in future SBI implementation projects and calls for new translational designs of 'personalized implementation' in order to match the individual providers needs and interest.^{15,17}

Screening rates

The proportion of patients screened varied across countries between 2 and 10% (Table 3), which is comparable with the WHO phase III study performed more than a decade ago.¹⁰ In the present study the median screening rate was 3% and the IQR 1-11%, compared to a median screening rate on 1% and IQR on 0-11% in the WHO phase III study. Although the number of participating providers and thereby eligible patients varied considerable between countries no systematic difference was seen concerning screening rate in each country (Table 3). However, in Catalonia where the numbers of eligible patients was far higher than in the remaining countries only 5% of the screened patients were screened positive in contrast to around 20-50% in the remaining countries (Table 4). This difference in screened positive might be explained by difference in the various countries concerning the average age of patients seeking PHC as well as frequency of visits.

Strengths and limitations

The strength of the present study is that it is an empirical study aiming at actually measuring the proportion of patients managed instead of a cross-sectional study where participants are asked to estimate the proportion of patient managed with hazardous or harmful drinking. However, a limitation is that we used self-completion tally sheets by staff or computerized medical records. Also, the included PHCU were heterogenic within and across countries, which on the other hand might reflect real practice.

Conclusion

Our study found no evidence that SBI rates were largely influenced by role security or therapeutic commitment. We only found a weak relationship between screening rate and higher role security. Given that the behaviour, as measured with SBI rates, has not changed much in the last decade in spite of increased policy emphasis, training initiatives and more research being published, this raises a question about what else is needed to increase implementation. The findings show that the studied factors are of lower importance for alcohol screening and BI rate and other factors such as clinical priorities, management support or workload might be more important for the implementation of SBI.

Another question to find answer to is what is an appropriate level of screening or if it is meaningful to try to increase screening rate more than the 5% level as found in this study.

The results of the forthcoming ODHIN implementation trial might give some new insight on the importance of the effect of three different implementation strategies (training plus support, financial reimbursement and referral opportunities to an internet-based brief advice programme) on screening and brief advice rates.¹⁸

These strategies might show to be more important than changing attitudes alone that have a modest relationship to activity. It may also be that we have not yet identified the key ingredient necessary for implementation. Should we be thinking about more direct marketing of SBI to the general population rather than relying on implementation via practitioners?

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6

Chapter 6

Improving the delivery of brief interventions for risky drinking in primary health care: outcome results of the ODHIN five country cluster randomised factorial trial

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An elaborated version of this manuscript has been in revision

Abstract

Objective: To evaluate the impact of training and support, financial reimbursement, and the option to refer to an internet-based method of giving advice (eBI) on primary health care providers' delivery of screening and advice to risky drinkers.

Design: Cluster randomised controlled factorial trial.

Setting: 120 primary health care units (PHCU) in Catalonia, England, the Netherlands, Poland and Sweden.

Participants: 746 PHCU general practitioners, nurses and practice assistants.

Interventions: PHCUs were randomised to one of eight groups: care as usual, training and support (TS), financial reimbursement (FR), and eBI; paired combinations of TS, FR and eBI, and all of FR, TS and eBI.

Outcome measures: Proportion of consulting adult patients given screening and brief intervention to reduce alcohol consumption.

Results: During a 4-week baseline measurement period, 11.3 per 1,000 adult patient consultations per PHCU were screened and advised to reduce their alcohol consumption. PHCU that received TS had a 69% relatively higher proportion of patients screened and advised during the 12-week implementation period than PHCU that did not receive TS; PHCU that received FR had a 125% relatively higher proportion. The option of referral to eBI was not associated with a higher proportion. A combination of TS plus FR was associated with a 280% relatively higher proportion of patients screened and advised compared to those PHCU that did not receive TS plus FR. This proportion was higher than the single strategies of TS or FR.

Conclusions: Combining TS plus FR showed highest relative proportion of patients screened and advised, but overall screening and brief intervention proportions were low. To increase brief advice activity in PHC for risky drinking, countries should offer specific training on dealing with risky drinking and could consider providing financial reimbursement to PHC providers for delivering screening and advice.

Introduction

Alcohol consumption is a wholly or contributory cause for more than 200 diseases, injuries and other health conditions with ICD-10 codes.¹ The cardio-protective effect of low-risk patterns of alcohol consumption disappears in the presence of heavy episodic drinking.² Globally, alcohol is the fifth most important risk factor for ill-health and premature death.³ Reduction in alcohol consumption is essential to achieve global targets of reducing deaths from non-communicable diseases by 25% between 2010 and 2025.⁴ Risky drinkers who reduce their drinking reduce their risk of mortality in comparison to those who continue risky drinking.^{5,6} The higher the level of drinking, the stronger the effects of a given reduction.⁷ Systematic reviews demonstrate that primary health care based screening and brief advice programmes are effective in reducing alcohol consumption and related harm.⁸⁻¹⁰

Many national and international guidelines recommend routine screening in primary health care and the offer of advice to screen positive patients.^(e.g. 11-13) However, in many countries there is a large gap between need and provision of advice. Elsewhere, we have shown that only 5.3% of eligible patients consulting their primary health care provider over a four-week period were screened for their alcohol consumption (average across Catalonia, England, Netherlands, Poland and Sweden).¹⁴ It is possible to close this gap. A meta-regression analysis of 29 studies found that professional, organisational and patient-oriented implementation strategies could improve screening (standardised effect 0.53;95%-CI 0.28-0.78) and advice (standardised effect 0.64;95%-CI 0.27-1.02) proportions.¹⁵

In this paper, we report on a five country study that tests the effectiveness of giving primary health care providers training and support and financial reimbursement for delivering screening and brief interventions (SBI) for risky drinking, and the option of referring identified risky drinking patients to an internet based method of delivering advice (eBI),¹⁶ on primary health care providers' proportions in delivering brief interventions to risky drinking patients. Two hypotheses were tested:

1. The provision of each of training and support, financial reimbursement, and eBI to primary health care providers will increase the proportion of patients screened and given a brief intervention, compared to no provision;
2. The combination of training and support, financial reimbursement, and eBI in pairs or all together will be more effective in increasing the proportion of patients screened and given a brief intervention compared to single-focused implementation strategies.

Methods

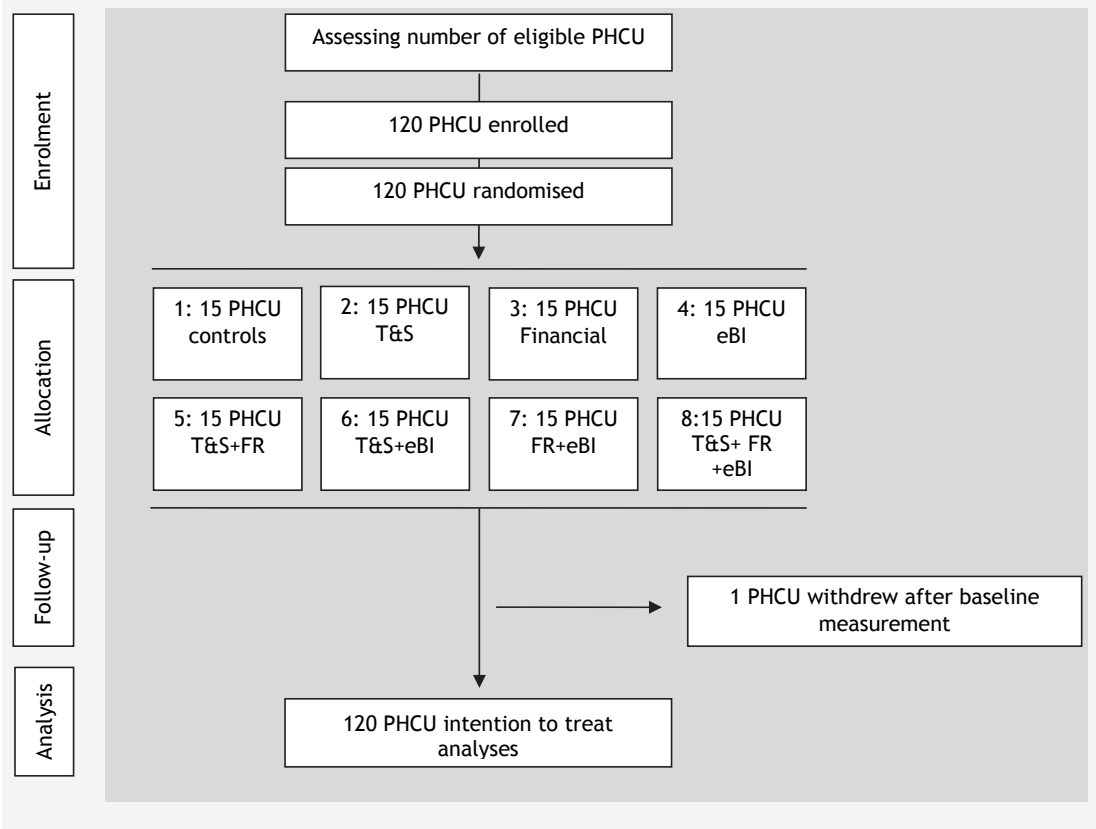
Implementation of the trial deviated from the protocol¹⁷ in three ways:

1. The outcome measure was revised into proportion of consulting adult patients given an intervention (screening and brief intervention to screen positives).
2. Since it is the PHCU that is the unit of randomisation and implementation, this paper reports only the PHCU as the unit of analysis, and not the individual provider as a separate level of analysis.
3. IBM SPSS v22 was used as the statistical package and not SAS V9.2.

Design

In a cluster randomised 2x2x2 factorial trial, the impact of the three different implementation strategies on screening and advice for risky drinking operationalised by AUDIT-C¹⁸ was studied (Fig. 1). Data were collected between August 2012 and December 2013.

Figure 1



Participants

PHCUs with approximately 5,000-20,000 registered patients were the unit of randomisation and implementation. PHCUs who agreed to participate in the study were volunteers drawn from administrative or academic registries of PHCUs at national or regional levels. Eligible providers in each PHCU included any fully trained full or part-time medical practitioner, nurse or PHCU assistant with a permanent appointment working in the PHCU.

Implementation strategies

PHCU were recruited between March and July 2013. After formal agreement of the PHCU to take part in the trial, a 4-week baseline measurement period took place. After a 2-6 week gap, the 12-week implementation period occurred, with the start date for each country between November 2012 and May 2013. All seven groups received the same input as controls but with additional components added.

1. *Control Group*: The control group was given a package containing a summary card of the national guideline recommendations for screening and advice for hazardous and harmful alcohol consumption, without demonstration. In Poland, the card was adapted from the PHEPA guidelines.^{19,20} Instructions were given on how to complete the trial record sheet, and providers were asked to screen all adult patients (aged 18+ years) with AUDIT-C.
2. *Training and support (TS)*: In addition to receiving the same package as the control group, the TS group was offered two initial 1-2 hours face-to-face educational trainings, and one (10-30 minutes) telephone support call to the lead PHCU contact person during the 12-week implementation period. Each country used an adapted existing country-based TS package. In Poland, the TS package was based on the PHEPA training programme.²¹
3. *Financial reimbursement (FR)*: The financial reimbursement group was paid for screening and advice activities (includes eBI) during the 12-week implementation period. In Catalonia, a maximum ceiling rate of €250 per provider was established, and fees were calculated based on the average individual performance of the 12-week implementation period. In England, fees were €6 per screening and €25 per advice, with a maximum ceiling rate of €2200 per PHCU. In the Netherlands, fees were €9 per screening and €13.50 per advice, with a maximum ceiling rate of €1250 per PHCU. In Poland, fees were €1.25 per screening and €10 per advice, with no ceiling rate. In Sweden, fees were €2 per screening and €15 per advice with a maximum ceiling rate of €3300 per PHCU.
4. *eBI*: In addition to receiving the same package as the control group, the eBI group was asked to refer identified at risk patients with an e-leaflet to an approved eBI

specific package, which was country specific, or, for Poland based on the WHO e-SBI programme.

5. *TS and financial reimbursement*: The TS and FR group received the control group package, training and support, and the financial reimbursement as described above.
6. *TS and eBI*: The TS and eBI group received the control group package, training and support as above, and were asked to refer identified at risk patients to eBI as above.
7. *Financial reimbursement and eBI*: The FR and eBI group received the control group package, were asked to refer identified at risk patients to eBI, and received financial reimbursement as described above.
8. *TS, financial reimbursement and eBI*: The TS, FR and eBI group received the control group package and training and support as above. They were asked to refer identified at risk patients to eBI and received financial reimbursement as described above.

PHCUs were asked to screen all adult patients (aged 18+ years) who consulted the PHCU using a paper version of AUDIT-C, except in Catalonia, where a computerised version was used. Screen positives were defined in Catalonia and England as men and women who scored ≥ 5 on AUDIT-C, and in Poland, Netherlands and Sweden as men who scored ≥ 5 and women who scored ≥ 4 on AUDIT-C. PHCU were asked to deliver brief advice of 5-15 minutes duration to screen positives, with the length and format of the advice based on country specific guidelines or, for Poland, the European guidelines developed by PHEPA.¹⁹ Providers who were allocated to eBI activity were asked to refer screen-positive patients to a computerised advice programme, taking a few minutes to explain why the patient ought to log on to the site.

Outcome measure

The outcome measure was the SBI proportions: proportion of consulting adult patients given an intervention (screening and advice to screen positives), i.e. number of AUDIT-C positive patients that received one or more of oral advice; an advice leaflet; referral to the eBI programme; or referral for advice to another provider in or outside the PHCU, divided by the total number of adult consultations of the participating providers per PHCU.

Randomisation and blinding

Randomisation took place after formal agreement of the PHCU to take part in the trial. The PHCUs were randomly allocated to one of the eight groups by the ODHIN coordinating centre, using computerised randomisation, stratified by country, ensuring 15 PHCUs per group (three per country). The research team and the PHCU were informed of the allocation after collection of the baseline measurement.

Sample size

It was estimated that 56 PHCUs (seven per eight allocation groups) with a minimum of 1,000 adult patient consultations per month would be needed for a 80% chance of detecting an increase in screening from 8% to 12% (intraclass correlation (ICC) = 0.029) and that 120 PHCUs (15 per eight allocation groups) would be needed for a 80% chance of detecting an increase in SBI proportion from 4% to 6% (ICC = 0.029) ($\alpha = 5\%$). As country was used as stratification criteria each country included a minimum of 24 PHCU. These estimates were based on published evidence of screening and advice proportions.²²

Statistical methods

The data analysed were the SBI proportions for the 12-week implementation period, controlling for the 4-week baseline period. We used a linear model that analyses change in proportions which are directly interpretable, as opposed to a logistic model that does not provide an interpretable size of effect. The study was a factorial design,²³⁻²⁵ based on the premise that the effect of TS instead of no TS can not only be estimated from TS vs control, but also from TS+FR vs FR, TS+eBI vs eBI, and TS+FR+eBI v FR+eBI, giving a pooled estimate with more precision.

Analyses were performed in IBM SPSS V22, using procedure MIXED with a random intercept and fixed variables that included the factors and baseline measurements. Models were analysed with random variable subject (country), as PHCU were nested within country. PHCU was the lowest level of analysis, not individual providers. There was an interaction between FR and eBI and the interaction term FR*eBI was entered in the models. SBI proportions are estimated marginal means per PHCU with 95% confidence intervals (95%-CI), accounting for PHCU within country. Contrast estimates were used to test for differences in mean proportion with and without the factor at baseline.

When examining the impact of the factors on the 12-week implementation proportions, examination of residuals found them to be not symmetrically distributed around 0, so log transformed data, which provided a better fit, were used. Prior to logging, proportions with a value of zero were assigned a value of 0.001. Since the data were logged, the contrast coefficients are relative effects.

Results**PHCU characteristics**

Across the five countries, 618 PHCU were contacted to achieve the sample of 120 PHCU (enrolment rate 19%, varying across countries: Catalonia 65%; England 7%; Netherlands 7%; Poland 46%; Sweden 24%). The number of registered patients averaged 10,000 across the 120 PHCUs. There was a mean of 1500 adult (age 18+ years) consultations per PHCU during the 4-week baseline period, mean age 53 years (SD=6), of whom 55%

were men. Just over half of the participating providers were doctors (55%), 38% nurses, and 7% practice assistants. The mean age of the participating providers per PHCU was 47 years (SD=5), and 74% were women.

During the 4-week baseline period, the proportion of screened patients that were screen positive based on AUDIT-C was 33.3% (95%-CI 18.8-47.8) per PHCU; this proportion did not differ between the presence and absence of the seven factors at baseline (results not shown). During the 4-week baseline period the SBI proportion was 11.3 per thousand (‰) (95%-CI 5.2-17.1) per PHCU. The baseline proportions for the outcomes did not differ statistically at baseline between the absence and presence of the factors, except for the SBI proportion for TS+eBI ($p<0.05$) and for TS+FR+eBI ($p<0.05$), Table 1.

Impact of implementation factors

Of the 120 PHCUs, one dropped out after the baseline measurement period (PHCU from Netherlands in FR group). For this PHCU, SBI proportions during the 12-week implementation period were set as the proportions for the baseline measurement period.

Table 1 displays the mean proportions (95%-CI) for SBI proportions for the baseline period and the implementation period, in the absence or presence of the factors, singly and in combination.

Table 1. Mean¹ SBI proportion (95%-CI) per PHCU with factor absent or present, singly and in combination over the measurement periods. NB: SBI proportions per thousand (‰)

Factor	Outcome	Factor absent or present	Baseline	Implementation period
TS	SBI proportion	Absent	12.2 (3.1-21.3)	10.3 (0-21.0)
		Present	10.4 (1.3-19.5)	17.5 (6.8-28.2)
FR	SBI proportion	Absent	12.8 (3.7-21.9)	9.1 (0-19.8)
		Present	9.8 (0.7-18.5)	18.7 (8.0-29.4)
eBI	SBI proportion	Absent	11.7 (2.6-20.7)	16.7 (6.0-27.4)
		Present	10.9 (1.8-20.0)	11.1 (0.5-21.8)
TS + FR	SBI proportion	Absent	12.1 (2.9-21.3)	10.4 (0-21.2)
		Present	8.9 (0-17.9)	24.5 (13.8-35.2)
TS + eBI	SBI proportion	Absent	12.3 (3.2-21.5)	14.2 (3.4-25.0)
		Present	8.2 (0-17.2) ²	13.1 (2.3-23.8)
FR + eBI	SBI proportion	Absent	12.0 (2.9-21.2)	14.3 (3.5-25.1)
		Present	9.1 (0.1-18.1)	12.7 (2.0-23.4)
FR + TS + eBI	SBI proportion	Absent	12.0 (2.7-21.1)	13.5 (2.6-24.3)
		Present	6.7 (0-15.9) ²	16.9 (5.4-28.5)

¹ Estimated marginal means accounting for multi-level nature of the data (PHCU within country)

² Contrast estimates found difference ($p<0.05$) in mean proportion between absence and presence of factor at baseline

TS: training and support; FR: financial reimbursement; eBI: internet-based method of giving advice

Table 2 displays the relative per cent difference (95%-CI) in 12-week implementation proportions in the presence as opposed to the absence of the factor, controlling for baseline proportions and accounting for the multi-level nature of the data (PHCU within country).

During the 12-week implementation period, the ICC for country was significant for the SBI proportions (0.40; 95%-CI 0.04- 0.76). The ICC for the proportion of AUDIT-C positives per screened patient during the 12-week implementation period was significant (ICC 0.73 95%-CI 0.44- 1.0). The ICCs for country were explained by the proportion of AUDIT-C positives per screened patient, and became no longer significant when the proportion of AUDIT-C positives per screened patient was included in the model for SBI proportions (0.35; 95%-CI 0.01- 0.70). The proportion of AUDIT-C positives per screened patient did not change over time and was not influenced by any of the factors (data not shown).

Table 2. Relative per cent difference¹ (95%-CI) in 12-week implementation proportions with factor as opposed to without factor (controlling for baseline proportions and accounting for multi-level nature of the data (PHCU within country))

	SBI proportions
TS	68.6*** (29.9 to 118.7)
FR	125.3*** (73.2 to 193.0)
eBI	-12.4 (-32.4 to 13.6)
TS + FR	279.7*** (161.6 to 451.2)
TS + eBI	47.7* (2.2 to 113.5)
FR + eBI	44.4 (-8.3 to 127.5)
FR + TS + eBI	143.5** (43.8 to 312.2)

¹ As an example, for the factor training and support and for the outcome SBI proportion, the 12-week proportion was 68.6% higher (95%-CI=29.9 to 118.7) with the factor (training and support) as opposed to without the factor. This is not the same as the factor increasing the baseline proportion by 68.6%.

* P<0.05; ** p<0.01; *** p<0.001

PHCU that received TS demonstrated a 69% (95%-CI 30- 119) relatively higher 12-week SBI proportion than PHCUs that did not receive TS. PHCU that received FR demonstrated a 125% (95%-CI 73- 193) relatively higher 12-week SBI proportion than PHCU that did not receive FR. Providing PHCU with the referral opportunity to eBI was not associated with a higher SBI proportion (the definition of SBI proportion included referral to eBI).

PHCU that received TS plus FR demonstrated a 280% (95%-CI 162- 451) relatively higher 12-week SBI proportion than PHCUs that did not receive TS plus FR. The combination of TS plus FR led to a 165.4% (95%-CI 80.8- 289.6) higher SBI proportion than TS alone (p<0.001) and to a 101.6% (95%-CI 41- 188) higher SBI proportion than financial reimbursement alone (p<0.001).

PHCU that received TS plus eBI demonstrated a 48% (95%-CI 2- 113) relatively higher 12-week SBI proportion than PHCUs that did not receive TS plus eBI. The combination of TS plus eBI led to a non-significant 28.6% (95%-CI 54.8- 12.6) lower SBI proportion than TS alone. The combination of FR and referral to eBI did not impact the SBI proportion (the definition of the SBI proportion included a referral to eBI).

PHCU that received TS plus FR plus eBI demonstrated a 144% (95%-CI 44- 312) relatively higher 12-week SBI proportion than PHCUs that did not receive TS plus FR plus eBI. The combination of TS plus FR plus eBI led to a non-significant 34.7% (95%-CI 62.4- 13.5) lower SBI proportion than training and support plus financial reimbursement alone.

Sensitivity analyses

The proportions dropped off during the 12-week implementation period (data not shown), so the analyses were rerun with the SBI proportions during weeks 9-12, controlling for baseline proportions. The relative per cent difference (95%-CI) in 9-12-week SBI proportions with factor as opposed to without factor for the three single factors were: TS 77.3% (27.7- 146.0); FR 92.3% (38.1- 167.8); and, eBI -19.5% (-42.0- 11.6).

The proportion of AUDIT-C positives per screened patient could be taken as a surrogate measure of country influences, and could reflect country differences in the proportion of risky drinkers. However, when including the proportion of AUDIT-C positives per screened patient in the model, no difference was made to our outcome results: for example, the relative per cent difference (95%-CI) in 12-week SBI proportion with factor as opposed to without factor for training and support was 65.3% (27.9- 113.5); and, for financial reimbursement was 129.0% (76.8- 196.6).

Discussion

Overall findings

During a 4-week baseline measurement period, brief advice for AUDIT-C screen positive patients was delivered by primary health care providers to 11.3 per 1,000 adult consultations. An AUDIT-C cut-off score of 5 is equivalent to a consumption level of about 20 grams of alcohol per day.²⁶ Amongst EU citizens aged 15-64 years, 230/1,000 women regularly drink 20 grams of alcohol or more per day and 300/1, 000 men regularly drink 40 grams of alcohol or more per day.²⁷ Of those screened in the ODHIN study, 330/1000 were AUDIT-C positive; this suggests that only some 3% of those who might benefit from brief interventions were receiving it.

In answering the first hypothesis, it was found that the provision of TS and of FR led to a higher proportion of consulting adult patients given advice. The offer of eBI referral did not impact this proportion. In answering the second hypothesis, it was

found that the combination of TS plus FR led to a higher proportion of consulting adult patients given advice than either TS or FR alone. We consider the lack of an impact of eBI due to a lack of familiarisation by the providers of eBI, and perhaps lack of trust in its impact. These negative views of eBI may have spilled over into the combined groups (with training and support and financial reimbursement), thus diminishing their impact.

The proportion of patients screened tended to jump during baseline and then tended to tail-off during the 12-week implementation period. The temporary increase is likely to be due to the 'Hawthorne effect' in which the PHCU improved their screening activity in response to their awareness of being measured. Thus, since the 12-week proportions may be inflated due to the 'Hawthorne effect', as part of sensitivity analyses, we re-ran the analysis, comparing the outcomes just for weeks 9-12 (the last four week block of the 12-week implementation period), and still found similar effects for TS and FR.

The proportion of screen positive patients given brief advice was very high at baseline (74%). This is likely to explain our inability to demonstrate an impact of TS and FR in changing the proportion of screen positive patients given brief advice.

Strengths and weaknesses

One strength of the present study is its factorial design, which ensured that it had sufficient power to detect small changes with a relatively small number of PHCU (N=120). Another strength of the study is that it was conducted across five different European countries, with differing health system financing and management structures. Sensitivity analyses found the results robust, with no evidence that provider or patient characteristics, including AUDIT-C positive proportions as a surrogate measure of risky drinking, that might have differed across countries, influenced the results.

One weakness of the present study was that the outcome measures were of provider behaviour, rather than patient outcomes. Another weakness of the study is that the record sheet to measure AUDIT-C included the options for giving advice. In itself, this is an organisational intervention to support provider behaviour that, whilst equal across all intervention groups, probably led to the high intervention proportions for positive screens (74%). Completion of the record sheet was made by the provider, and the study had no independent check that the advice was actually carried out, or that a screen or advice were done without being registered on the record sheet. Another weakness of the study is the short time span of the implementation period. Resourcing of the study constrained the implementation period to twelve weeks.

Comparison with other studies

The impact of TS is similar to the results of the World Health Organization four country (Australia, Belgium, Catalonia and England) collaborative randomised controlled trial which demonstrated the effectiveness of TS in promoting screening and intervention for hazardous and harmful alcohol consumption.^{22,28} In the WHO study, the odds ratios for the impact of high TS on increasing higher screening proportions (defined as 20% or more) was 2.2 (95% CI=1.3 to 3.1) and on increasing higher intervention proportions (defined as 10% or more) was 2.8 (95% CI = 1.6 to 4.0).³²

In contrast, a cluster randomised controlled trial in the Netherlands, which investigated the impact of an improvement programme combining professional, organisation, and patient directed activities, failed to find an impact of the intervention on the number of adult patients who received screening and advice.²⁹ One of the given reasons for failing to find an impact was sub-optimal implementation of the programme due to difficulties in recruiting GPs and in motivating GPs for participation in the tailored parts of the programme.

Implications for service commissioners and policy makers

The potential of SBI programmes to improve health (and sometimes to reduce costs) has been shown elsewhere.^{30,31} With strong government support for alcohol brief interventions, reinforced by financial and performance management arrangements, guidance and strategic leadership, as well as training, it is possible to increase alcohol SBI.^{13,32-34}

We included the option of referral to an eBI programme as one of the implementation strategies in the belief that this might encourage higher screening activity, as providers did not then have to deliver a brief advice themselves. The failure of this strategy to impact on any of the outcomes would suggest that providers in this study are not yet ready to refer patients to eBI programmes. Elsewhere, we have shown that providers who more strongly believe that risky drinking is the drinker's own responsibility report that they are less likely to engage in delivering brief advice.³⁵ Thus, for the time being, it might be preferable to market eBI programmes directly to drinkers, rather than through their primary health care providers, whilst more studies are undertaken to explore how referral to eBI could be best organised and implemented.

Based on the ODHIN findings, we would recommend that all countries could consider providing support for alcohol brief intervention based on training and guidance, financial and performance management arrangements, and strategic leadership, so as to increase the volume of brief interventions delivered to risky drinking patients in primary health care.

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Chapter 7

*Impact of primary healthcare providers' demographics,
initial role security and therapeutic commitment and
working conditions on implementing brief interventions
in managing risky alcohol consumption:
a cluster randomised factorial trial*

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Abstract

Background: Brief interventions in primary healthcare to detect and intervene in risky alcohol consumption are cost-effective in reducing drinking problems, but poorly implemented in routine care. Although evidence about implementing brief interventions is growing, knowledge is limited concerning provider-related factors influencing brief intervention implementation, such as demographics, initial role security and therapeutic commitment, and working conditions.

Methods: In a cluster randomised factorial trial 120 Primary Healthcare Units (PHCUs) were randomised to eight groups: care as usual, training and support, financial reimbursement, and referral to e-BI; paired combinations of these three strategies, and all three strategies combined. To explore the impact of provider-related factors on implementing brief interventions, eight provider characteristics were examined: demographics as age, gender, occupation; pre-trial role security and therapeutic commitment; and working conditions as PHCU type, number of PHCU registered patients, and number of consulting adult patients per provider.

Results: Data from 746 providers of 120 PHCUs were included in the analyses. The gender, age, occupation, baseline role security and therapeutic commitment were found not to influence implementation of brief interventions. PHCU type influenced implementation of brief interventions and interacted with financial reimbursement; financial reimbursement was only effective at solo and duo PHCUs. Also the number of patient consultations interacted with financial reimbursement; financial reimbursement was only effective in providers who were in the top half of number of patient consultations.

Conclusions: Most provider characteristics, including pre-trial role security and therapeutic commitment, had no impact on implementing brief interventions. However, PHCU type and number of provider consultations did have influence. This insight helps to tailor implementation strategies to the different settings in which providers are delivering healthcare and suggest that a more professionalised or businesslike approach might be required in implementing brief interventions.

Background

The World Health Organization Status Report on Alcohol and Health documented that the level of alcohol consumption in the European Union (EU) is almost double the global average, as on average almost 2.5 alcoholic drinks (25 grams) are consumed every day.¹ Alcohol is an attributable cause of more than 200 International Classification of Disease (ICD)-10 codes² and, in the age group of 15-49 years, it is the leading risk factor for the global burden of disease.³ In Europe, 1 in every 7 deaths in men and 1 in every 13 deaths in women in the group aged 15-64 years is due to alcohol consumption.³

In primary healthcare, screening and brief interventions (SBI) to detect and intervene in risky alcohol consumption are cost-effective in reducing alcohol consumption.⁴ However, SBI are poorly implemented in primary healthcare settings.⁵⁻⁸ Reasons for this include providers' lack of knowledge, low role security and therapeutic commitment, lack of financial resources and lack of time.^{9,10} In due course there have been several studies undertaken on methods to overcome these barriers with implementation strategies to embed SBI in routine care¹¹⁻¹³, but evidence for optimally designed implementation strategies for a wider uptake of SBI, remains inconclusive.¹⁴

With more knowledge on factors that facilitate or hinder implementation, one will be able to adapt to and take these into account within implementation programmes. The ODHIN trial (Optimizing Delivery of Healthcare Interventions; www.odhinproject.eu) increases our knowledge on best methods for improving brief interventions' frequency in primary healthcare. This trial concerned a multifaceted programme to implement brief interventions in routine primary healthcare, using specific training and support on how to deal with alcohol-related problems, financial reimbursement and the opportunity to refer patients to an internet-based brief intervention (e-BI) as strategies. The trial showed that the highest increase in brief intervention proportions was present in the primary healthcare units (PHCUs) that received training and support combined with financial reimbursement. These combined implementation approaches significantly increased brief intervention proportions from 8.7 per 1,000 adult consultations at baseline to 24.5 per 1,000 after implementation (a 280% increase).¹⁵

To date, it is unclear which provider characteristics influence implementing brief interventions for risky alcohol consumption. Candidate factors include the age, gender and occupation of providers, and working conditions such as the type of PHCU (solo [i.e. single handed GP in one PCHU], duo [i.e. two GPs in one PCHU], group practice or health centre), the number of PHCU registered patients or the number of provider patient consultations.^{9,10,16-18} It also remains unclear to what extent primary healthcare providers' role security and therapeutic commitment impact on the brief intervention implementation. Previous research has shown that General Practitioners (GPs) with greater role security and therapeutic commitment towards patients with risky alcohol consumption, report being more involved in managing alcohol-related problems than

others.^{19,20} A recent survey in eight European countries showed that physicians who had received more education on alcohol and physicians who had higher role security and therapeutic commitment, reported managing a higher number of patients for alcohol and alcohol problems.¹⁰ If providers' baseline role security and therapeutic commitment are not accounted for in implementation programmes, interventions can lead to a deterioration in role security and therapeutic commitment.¹⁹ However, another trial showed a lack of improvement in role security and brief intervention proportions despite the extended implementation program.²¹

Based on the current evidence base, we hypothesised that higher baseline role security and therapeutic commitment would result in greater implementation of brief interventions.^{10,21} In addition, we hypothesised that lower age, female providers, practice nurses, health clinics and a lower number of patient population and consultations would be associated with higher implemented brief intervention proportions.^{9,10,16,17} Therefore, the aim of this paper was to evaluate the influence of provider-related characteristics, with particular focus on providers' initial role security and therapeutic commitment, on the level of implementing brief interventions.

Methods

This paper builds on the findings from the ODHIN trial which was focused on identifying implementation strategies for implementing brief interventions.¹⁵ CONSORT guidelines were followed in reporting the trial.²²

Study design and participants

ODHIN was a cluster randomised 2x2x2 factorial trial as described in the study protocol (ClinicalTrials.gov. Trial identifier: NCT01501552).²³ English, Catalan, Polish, Swedish and Dutch PHCUs participated and combined their data to examine the effect of three different implementation strategies (training and support, financial reimbursement and referral opportunities to an internet-based brief intervention program) on brief intervention implementation proportions for risky drinkers identified by screening using the AUDIT-C questionnaire screening tool.²⁴

PHCUs who agreed to participate in the study were volunteers drawn from administrative or academic registries of PHCUs at national or regional levels. Eligible providers in each PHCU included any fully trained GP, nurse or practice assistant with a non-temporary employment contract working in the PHCU and involved in medical and/or preventive care. In Poland, only GPs participated in the study. Since Polish providers normally operate as single-handed entities working with other providers in one building, three providers and their staff working in one building was regarded as one PHCU. In each country, approval of the national ethics committee was obtained when applicable.

Implementation strategies

After formal agreement of the PHCUs to take part in the trial, a four week baseline measurement took place, during which no trial interventions were administered. After a 2-6 week gap, the twelve-week implementation period occurred with the start date for each country between November 2012 and May 2013. All seven allocation groups received the same input as controls but with additional components added.

1. Control group: care as usual
2. Training and support (TS)
3. Financial reimbursement (FR)
4. Referral to internet-based brief interventions (e-BI)
5. T&S and FR
6. T&S and e-BI
7. FR and e-BI
8. T&S, FR and e-BI

More details about the implementation strategies and procedural activities were described in Additional file 1.^{23,15}

Measures

Brief intervention proportions

Brief intervention proportions were the primary outcome of the ODHIN study. These were measured at four time points: during the 4-week baseline period, and during each of the three consecutive 4-week blocks during the 12-week implementation period. Paper tally sheets were completed by the providers, with the exception of Catalonia, where electronic patient records were completed by the providers. The tally sheets included AUDIT-C questions, AUDIT-C scores, and tick boxes to indicate the type of intervention (oral advice, an advice leaflet, referral to the e-BI program, or referral for advice to another provider in or outside the PHCU) that was delivered. The 12-week proportions were calculated as the mean of the three 4-week implementation phase blocks, with, in the case of missing data from any of the three blocks, the mean calculated from the blocks that contained data. For the one PHCU that dropped out of the study after the baseline measurement, and the two PHCUs that failed to provide data for any of the three 4-week blocks during the 12-week implementation period, data outcome measurements during the 12-week implementation period were set as the proportions for the baseline measurement period in an intention to treat analysis.

The brief intervention proportions were calculated as number of AUDIT-C positive patients that received one or more of oral advice, an advice leaflet, referral to the e-BI program, or referral for advice to another provider in or outside the PHCUs, divided by the total number of adult (≥ 18 years) consultations by the participating providers per PHCU.

Provider characteristics: demographics, role security and therapeutic commitment and working conditions

Before starting the baseline measurement of brief interventions, providers completed a questionnaire in which they provided their demographical features, including gender, age and occupation (e.g. medical practitioner, nurse, practice assistant, etc).

Fourth and fifth variables of interest were providers' role security and therapeutic commitment, which were measured at baseline by the short version of the Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ), translated to the native language of each participating country.²⁵ All participating providers who provided written informed consent were asked to complete the SAAPPQ. Role security measures role adequacy, for example "I feel I can appropriately advise my patients about drinking and its effects"; and role legitimacy, for example, "I feel I have the right to ask patients questions about their drinking when necessary". Role security is expressed at the emotional level, whereas therapeutic commitment measures motivation, for example "pessimism is the most realistic attitude to take toward drinkers"; task specific self-esteem, for example "all in all I am inclined to feel I am a failure with drinkers"; and work satisfaction, for example "in general, it is rewarding to work with drinkers". Role security includes four items on a 7-point Likert scale and summed scores range between 4 and 28. Therapeutic commitment includes six items on a 7-point Likert scale and summed scores range between 6 and 42.

Sixth, seventh and eighth variables of interest were variables concerning the working conditions of each participating provider: PHCU type (solo [i.e. single handed GP practitioner in one PCHU], duo [i.e. two GP practitioners in one PCHU], group practice or health centre), size of registered patients within the practice, and the number of consulting adult patients per provider during the 4-week baseline period. The research team was informed about these variables at baseline measurement.

Sample size and randomisation

To achieve sufficient statistical power for significant effects on intervention proportions, it was estimated that 120 PHCUs (15 per eight allocation groups, evenly distributed between countries) would be needed.²³

Randomisation took place after formal agreement of the PHCUs to take part in the trial. The PHCUs were randomly allocated to one of the eight allocated groups by the ODHIN coordinating centre, using computerised randomisation, stratified by country (i.e. block randomisation), ensuring 15 PHCUs per group (three per group in each country).²³

Statistical analysis

Because of the hierarchical structure (providers nested within PHCU, nested within country), we performed a 2 level linear multilevel analysis (mixed model). We

performed a model with a random intercept for countries and practices and other variables such as TS, FR, e-BI, and baseline brief intervention proportions fixed. The outcome measure was brief intervention proportions after the implementation period. Multiple imputation was not applied as the percentage of missing cases was 1.5%.²⁶

When examining the impact of the implementation factors on the 12-week brief intervention proportions, examination of residuals found them to be not symmetrically distributed around zero, so the data underwent log transformation, which provided a better fit. Prior to log transformation, proportions with a value of zero were assigned a value of 0.001. Coefficients for the combined effects of TS+FR and TS+e-BI were the sum of the individual coefficients. Since the data were log transformed, the contrast coefficients are relative effects. The percentage difference in brief intervention proportions with each implementation strategy as opposed to without, were calculated with the equation: $\text{difference(\%)} = 100 * (\exp(2 * \text{coefficient estimate from procedure MIXED}) - 1)$.

To test the influence of the defined eight provider characteristics on the implemented brief interventions, the model was run with the provider characteristics collected at baseline, included one by one (gender, age, occupation, role security, therapeutic commitment, PHCU type, number of PHCU registered patients and number of consulting adult patient per provider). Furthermore, for each of the eight provider characteristics we added interaction terms in order to identify interactive effects of characteristics with the implementation strategies. We considered a p-value <0.05 statistically significant. In case of interaction, subgroups of variables were analysed separately. Last, correlations between the eight variables were tested with Pearson's correlation test. The statistical analyses were performed with IBM SPSS v20. The datasets are available upon request.

Results

Study population

Figure 1 outlines the flow of participating PHCUs and providers throughout the parent trial. The 120 participating PHCUs with 746 providers were randomised and included in the analyses.

Figure 1. Trial flow chart

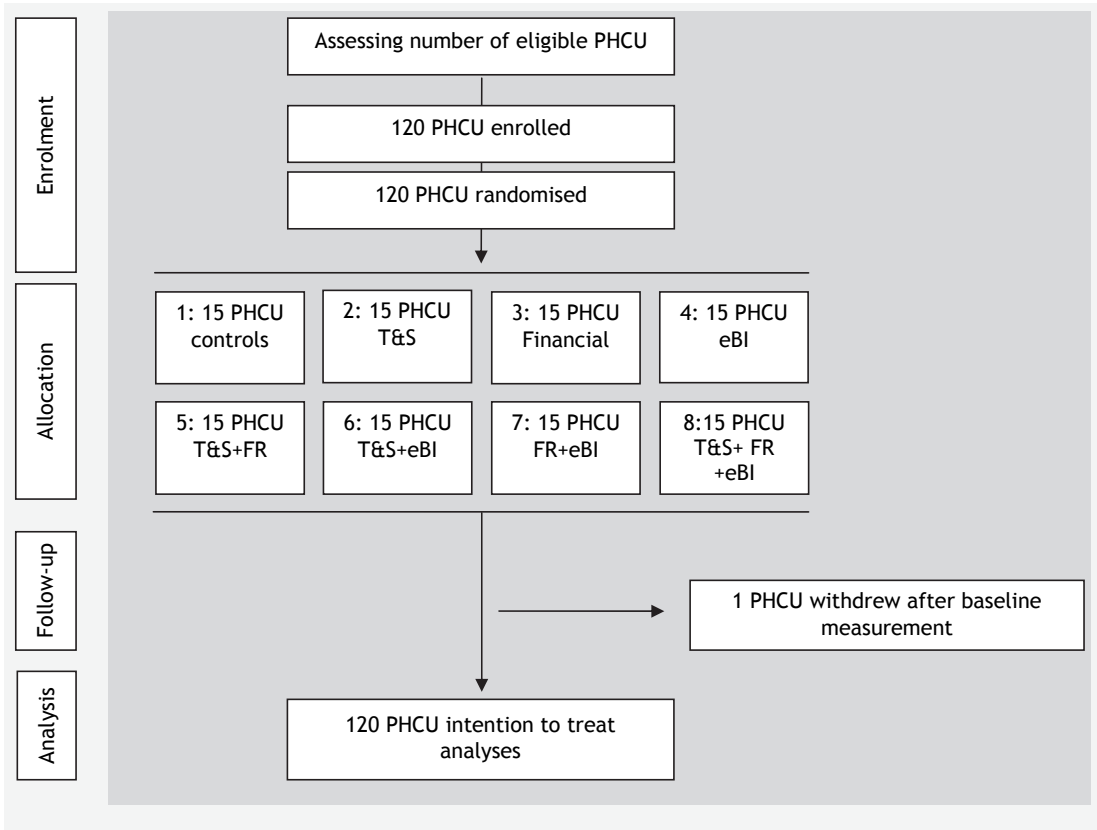


Table 1 shows baseline characteristics of participating providers. Almost three quarters of the participating providers were women and the mean age of all participating providers was 47.0 years (SD 9.4). Occupations of participants varied, though participants were mainly GPs or nurses. Most participating providers were employed in health clinics and group practices. The mean number of consulting adult patients per month per provider during the baseline was 242, but varied greatly between providers with a standard deviation of 188. Role security was high at baseline, with a score of 21.0 (SD 3.5) within a possible range of 4-28. Regarding therapeutic commitment, scores were relatively low with a score of 27.2 (SD 4.7) within a possible range of 6-42. There were no baseline differences observed between any of the eight allocation groups, however PHCU type, the number of registered patients in the PHCU and the number of consulting adult patients per provider were significantly correlated with each other (health centres had the highest number of registered patients and consultations and solo practices the lowest) (all $p < 0.05$).

Table 1. Characteristics of participating providers

Characteristic	All participants (n=746)*
N (%) of women	559 (74.9)
Mean (SD) age in years	47.0 (9.4)
Occupation (%)	
- GP	- 54.7
- Nurse	- 37.8
- Practice assistant	- 5.1
- Other	- 2.3
Type of PHCU** (%)	
- Solo	- 26 PHCUs (21.7%); 72 providers (9.7%)
- Duo	- 13 PHCUs (10.8%) 67 providers (9.0%)
- Group	- 23 PHCUs (19.2%) 132 providers (17.7%)
- Health Clinic	- 58 PHCUs (48.3%) 475 providers (63.7%)
Mean number of registered patients in PHCU (SD)	10,543 (4,909)
Mean number of consultations of eligible patients (18 and over) at baseline (SD)	242 (188)
Mean role security*** (SD)	
- Baseline	21.0 (3.5)
Mean therapeutic commitment**** (SD)	
- Baseline	27.2 (4.7)

* No differences in baseline measures. The analyses to check for differences in baseline measures between allocation groups took into account nested nature of the data

**PHCU=Primary Healthcare Unit. In Poland, providers normally operate as single-handed entities working with other providers in one building, three providers and their staff working in one building was regarded as one PHCU

***Score at minimum 4; at maximum 28

****Score at minimum 6; at maximum 42

Influence of provider demographic characteristics on implementation

Including the demographic characteristics gender, age and occupation in the statistical model had no statistically significant impact on the brief intervention proportions after the implementation period. Furthermore, gender, age and occupation showed no interactions with group allocation, meaning that effects of the implementation strategies did not differ by gender, age or occupation (data not shown). There were no correlations between demographic characteristics.

Influence of baseline role security and therapeutic commitment on implementation

Baseline role security and therapeutic commitment were significantly correlated ($p < 0.001$). Testing the influence of providers' role security and therapeutic commitment towards dealing with risky drinking prior to the trial, that is, their baseline role security and therapeutic commitment, taking account of the correlation between these factors, showed that neither have a significant influence on brief intervention implementation. Also there were no significant interactions between these factors and allocated groups.

Influence of working conditions on implementation

After including the number of PHCU registered patients, PHCU type and number of adult patients consulting per provider into the statistical model, only PHCU type influenced brief intervention outcomes. However, since PHCU type, number of PHCU registered patients and number of adult patients consulting per provider were significantly inter-correlated, these were controlled for in the statistical model. Table 2 shows the basic model which reports implementation strategy effects on brief interventions, secondly including PHCU type, and then shows the final model including PHCU type, number of registered patients per PHCU and number of adult patients consulting per provider.

Furthermore, there was interaction by type of PHCU ($p=0.011$) and by number of provider consultations ($p<0.001$) for the FR allocations, which means that effects of implementation strategies differed by type of practice and by number of patient consultations. In solo and duo practices, the effects of FR as well as FR combined with T&S and e-BI show significant interactions (table 3). In group practices and health centres there were no effects of FR singly and in combination only in group practices. Concerning interaction effects by number of provider consultations, for those providers with the lower half of number of consultations up to 242 consultations in four weeks, there is no effect of FR. Only combining FR with T&S or e-BI improved their brief intervention proportions significantly. For those providers with 243 or more consultations in four weeks time, analyses showed that FR actually do increase providers' brief intervention proportions in single and in combined approaches with T&S or e-BI.

Table 2. Relative per cent difference in implemented brief intervention proportions compared to baseline, specified by implementation strategy

Implementation component	Basic model: brief intervention proportion difference (95%-CI; p-value)*	Basic + PHCU type: brief intervention proportion difference (95%-CI; p-value)*	Final model = basic+PHCU type+practice size+N consultations: brief intervention proportion difference (95%-CI; p-value)*
Training & Support (TS)	60.4 (14.5-124.8; 0.007)	47.8 (8.2-102.0; 0.015)	47.1 (12.2-92.9; 0.006)
Financial reimbursement (FR)	68.8 (20.5-136.6; 0.003)	66.0 (21.7-126.3; 0.002)	68.6 (28.6-121.1; 0.000)
e-BI	4.9 (-25.1-47; 0.78)	8.3 (-20.5-47.7; 0.610)	7.2 (-18.3-40.6; 0.614)
TS plus FR	170.7 (68.7-334.6; <0.001)	145.4 (58.5-279.8; <0.001)	148.0 (69.3-263.2; 0.000)
TS plus e-BI	68.3 (4.1-172.2; 0.034)	60.2 (2.9-149.2; 0.037)	57.6 (7.3-131.7; 0.021)
FR plus e-BI	77.1 (10.6-183.7; 0.018)	79.8 (16.7-176.9; 0.008)	80.7 (24.2-162.9; 0.002)
T&S plus FR plus e-BI	184.1 (59.2-407.0; 0.001)	165.8 (56.1-352.7; <0.001)	165.8 (67.4-322.0; 0.000)

*Adjusted for baseline brief intervention proportions and accounting for providers nested within PHCU nested within country

Table 3. Relative per cent difference in 12-week implementation proportions from baseline, by PHCU type

Intervention component	26 solo practices (95%-CI; p-value)*	13 duo practices (95%-CI; p-value)*	23 group practices (95%-CI; p-value)*	58 health centres (95%-CI; p-value)*	Providers with lower half of patient consultations**	Providers with upper half of patient consultations**
Financial reimbursement (FR)	200.1 (66.9-439.8; 0.001) [#]	575.6 (138.9-1810.8; 0.005) [#]	53.1 (-14.37-174.7; 0.140)	25.8 (-12.0-79.7; 0.202)	35.1 (-5.8-93.8; 0.101)	135.0 (79.7-207.3; <0.001) [#]
TS plus FR	419.7 (128.6-1081.3; 0.001) [#]	969.8 (114.0-5248.6; 0.015) [#]	133.5 (1.9-435.1; 0.046) [#]	49.9 (-10.0-149.9; 0.117)	82.4 (10.1-202.3; 0.020) [#]	243.8 (134.7-403.6; <0.001) [#]
T&S plus FR plus e-BI	146.8 (-9.5-573.2; 0.075) [#]	890.1 (23.6-7830.1; 0.038) [#]	252.8 (22.3-917.9; 0.023) [#]	80.8 (-0.7-229.1; 0.053)	114.6 (16.8-294.4; 0.015) [#]	226.2 (103.2-423.8; <0.001) [#]

*Adjusted for baseline brief intervention proportions, number of PHCU registered patients, number of provider consultations and accounting for providers nested within PHCU nested within country

** Adjusted for baseline brief intervention proportions, number of PHCU registered patients, PHCU type and accounting for providers nested within PHCU nested within country; lower half of patient consultation numbers = 0-242 patient consultations in four weeks time; upper half of patient consultation numbers= ≥243 patient consultations in four weeks time, cut-off by the mean

[#] Significant effect

Discussion

The aim of this paper was to evaluate the influence of primary healthcare provider-related factors, with particular focus on baseline role security and therapeutic commitment, on the impact of implementing brief interventions. Baseline role security and therapeutic commitment both appeared to have no influence on implementation of brief interventions in this study. Also age, gender and occupation had no influence. However, the PHCU type did have a significant effect on implementing brief interventions. Furthermore, with regard to interaction effects, none were found between T&S or e-BI and provider-related demographics or attitudes, although effects of FR differed by PHCU and by number of provider consultations. In solo and duo PHCUs there were highly significant increases on brief intervention proportions, whereas in group practices and health centres FR had no effect. Regarding the number of adult patient consulting per provider, FR was only effective in providers who were in the upper half of number of patient consultations in four weeks time.

In this study, the financial reimbursement scheme differed per country. In Poland and Catalonia, providers were reimbursement directly, whereas in Sweden and the Netherlands reimbursement was applied on PHCU level. If financial reimbursement was paid in all countries at the PHCU level rather than on individual providers, then one might find it logical that financial reimbursement worked suboptimal for providers in group practices or health clinics, compared to solo and duo practices. Catalonia and Sweden both included 24 health centres each, however with different reimbursement schemes. We cannot explain the process behind, as it could not be the country itself causing the effect, because the multilevel analysis model accounted for providers nested within PHCUs, nested within country. Reviews support the view of still unexplained processes.²⁷ Nevertheless, the finding that FR was only effective in those providers with high numbers of patient consultations, might incline that FR is only effective in those providers that take significant advantage in terms of money, from being reimbursed and thus could suggest a more professionalised or businesslike approach being required. Therefore we suggest to conduct more research about implementation processes in this context. In future research, we suggest to also pay attention for unintended consequences, such as decreased quality of care, as this was not a topic of interest in this study.^{27,28} Additionally, it is also reported that pay for performance indeed can be used to improve the quality of care, however it is not a “magic bullet” and so should be combined with other quality improvement initiatives.²⁸ Subsequently, it should be noted that the solo practices in our dataset were overrepresented by Poland, and therefore there might be other Poland-related influences of importance as well. Furthermore, this study was powered on 120 PHCUs and therefore the absence of financial reimbursement effects for group practices and health clinics should be interpreted with caution.

Despite our finding that PHCU type does matter when implementing brief interventions, the number of PHCU registered patients (e.g. practice size) did not have influence. This is partly in line with outcomes of Ng et al 2013 review¹⁸, in which supportive evidence of practice size on quality of care was only found for half of the included studies. This could incline that PHCU type is not of influence because of the size - in our study, health centres had the highest number of registered patients and consultations and solo practices the lowest - but potentially because of other factors, such as a greater variety of staff and therefore a more diverse role function.

The hypothesis that baseline provider's role security and therapeutic commitment have impact on the number of patients managed for their risky alcohol consumption^{10,19,20}, was not confirmed by this study. Furthermore, in this study the training and support strategy is both effective for providers with low and high baseline role security and therapeutic commitment, in contrast to the findings of Anderson et al where levels even deteriorated for those with low levels at baseline.¹⁹ In addition, as brief intervention proportions were significantly improved in this study, one might question the importance of role security and therapeutic commitment in the implementation process. However, besides possible ceiling effects of the instrument, we must acknowledge that in this study only baseline role security and therapeutic commitment was included, though these can evolve over time. So our finding does not rule out there being any importance of these factors, but merely indicate that the extent to which providers' managed to change their brief intervention proportions when submitted to different implementation strategies was not determined by their initial attitudes towards alcohol problems. In future research more attention is needed for the causal relation between these parameters, as it can inform us whether to focus on these or not in implementation trajectories.

The study had strengths and limitations. The implementation strategies were applied in all five countries, but the specific content was tailored to the country context. For example, e-BI was designed in country-specific packages. Also the financial reimbursements were adapted to country standards.²⁹ To preserve comparability between countries, we formulated minimum requirements that country specific implementation strategies had to meet. For the remainder, countries had flexibility in making the strategies compatible with country standards. Therefore, we think that these results are valuable for each country's policy makers, especially with outcomes of this process analyses. Another strength was the hierarchical structure of individual providers being nested within PHCU, and PHCU being nested within country, which was taken into account in the analyses. Lastly, the five participating countries differ in their organisation of primary healthcare and in their burden of alcohol consumption as well as their drinking patterns. Therefore, our findings could be generalised to other western countries as well.

A limitation of the study is the lack of patients' alcohol consumption measurements following intervention. A systematic review showed that positive impact of implementation strategies on provider behaviour does not automatically cause decrease alcohol consumption as well.³⁰ Therefore, we recommend future research to include both provider and patient measurements. Another limitation of the study is the lack of results concerning the country specific effects of our implementation strategies, as the study was powered on the total of five countries. So, the country specific strengths of effects remain unknown due to insufficient data as this was not the primary goal of this international study. Furthermore, more research is needed to explore whether our finding that financial reimbursement is associated with significant increases in brief intervention proportions in solo and duo practices, are representative.

Conclusions

In this study, providers' baseline role security and therapeutic commitment had no discernible impact on implementing brief interventions. Furthermore, implementing training and support and e-BI is not influenced by provider-related characteristics, though financial reimbursement effects varied by PHCU type and by numbers of adult patients consulting per provider, being only effective in solo and duo practices and in providers with relative high numbers of patient consultations. This insight helps to tailor implementation strategies to provider characteristics, in particular their working conditions, and suggests that a more professionalised or businesslike approach is required in implementing brief interventions.

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Additional file 1: Detailed description of applied implementation strategies.

Allocation groups	
1. Usual care	The control group received a package containing a summary card of the national guideline recommendation for screening and brief intervention for hazardous and harmful alcohol consumption, without demonstration. In Poland, where no national guidelines existed, the summary card was adapted from the PHEPA guidelines for the purposes of this trial [1]. No further instructions were given.
2. Training and support (TS)	In addition to receiving the same package as the control group, the TS group were offered two initial 1-2 hours face-to-face educational trainings, and in between the training sessions one (10-30 minutes) telephone support call to the lead PHCU contact person during the twelve week implementation period. If necessary one additional face-to-face training of 1-2 hours duration was offered. The time intervals between the initial training, the telephone call, and the additional optional training were, on average, two weeks. The training addressed knowledge, skills, attitudes, and perceived barriers and facilitators in implementing screening and brief interventions, combining theory and practical exercises. During the contact moment with practices, trainers tailored to the baseline attitudes of providers and discussed their experienced barriers and facilitators. For instance, final content of the second training session was adapted according the issues raised during the telephone support call. More details can be found in the published study protocol.
3. Financial reimbursement	Financial reimbursement groups were paid for screening and brief intervention activities, with proportions based on existing country-specific financial reimbursement for clinical preventive activities and were therefore in line with country standards. In Catalonia, a maximum ceiling rate of €250 per provider was established, and fees were calculated based on the average individual performance of the 12-week implementation period. A minimum proportion had to be met in order to receive any payment, and above this rate, the amount increased proportionally up until the maximum of €250 euros. In England, fees were €6 per screening and €25 per brief intervention, with a maximum ceiling rate of €2200 per provider unit. In Poland, fees were €1.25 per screening and €10 per brief intervention, with no ceiling rate. In The Netherlands, fees were €9 per screening and €13,50 per brief intervention with a maximum ceiling rate of €1250 per provider unit.
4. e-BI	In addition to receiving the same package as the control group, the e-BI group were asked to refer identified at risk patients with an e-leaflet with unique log in codes to an approved e-BI specific package, which was country specific, or, for Poland based on the WHO e-SBI programme. The website included: log in facility to allow monitoring of the patient (i.e. patient actually log-in); suitable brief screening tool with ability to calculate score and give feedback (i.e. brief intervention); appropriate information on sensible drinking guidelines; information on impact of alcohol on health and wellbeing; and a drink diary facility.
5. TS and financial reimbursement	The TS and financial reimbursement group received the control group package, training plus support and the financial reimbursement as described above.
6. TS and e-BI	The TS and e-BI group received the control group package, training plus support as above, and were asked to refer identified at risk patients to e-BI as above.
7. Financial reimbursement and e-BI	The financial reimbursement and e-BI group received the control group package and were asked to refer identified at risk patients to e-BI as above. They were paid for screening, referral performance to e-BI, and brief intervention if actually delivered, with the system of pay as above.
8. TS, financial reimbursement and e-BI	The TS, financial reimbursement and e-BI group received the control group package and training plus support as above. They were asked to refer identified at risk patients to e-BI as above. They were paid for screening, brief intervention activities, and referral performance to e-BI, with the system of pay as above.

8

Chapter 8

Strategies in primary healthcare to implement early identification of risky alcohol consumption: why do they work or not? A qualitative evaluation of the ODHIN study

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Abstract

Background: Screening and brief interventions (SBI) in primary healthcare are cost-effective in risky drinkers, yet they are not offered to all eligible patients. This qualitative study aimed to provide more insight into the factors and mechanisms of *why, how, for whom* and *under what circumstances* implementation strategies work or do not work in increasing SBI.

Methods: Semi-structured interviews were conducted between February and July 2014 with 40 GPs and 28 nurses in Catalonia, the Netherlands, Poland, and Sweden. Participants were purposefully selected from the European Optimising Delivery of Healthcare Interventions (ODHIN) trial. This randomised controlled trial evaluated the influence of training and support, financial reimbursement and an internet-based method of delivering advice on SBI. Amongst them were 38 providers with a high screening performance and 30 with a low screening performance from different allocation groups. Realist evaluation was combined with the Tailored Implementation for Chronic Diseases framework for identification of implementation determinants to guide the interviews and analysis. Transcripts were analysed thematically with the diagram affinity method.

Results: Training and support motivated SBI by improved knowledge, skills and prioritisation. Continuous provision, sufficient time to learn intervention techniques and to tailor to individual experienced barriers, seemed important T&S conditions. Catalan and Polish professionals perceived financial reimbursement to be an additional stimulating factor as well, as effects on SBI were smoothened by personnel levels and salary levels. Structural payment for preventive services rather than a temporary project based payment, might have increased the effects of financial reimbursement. Implementing e-BI seem to require more guidance than was delivered in ODHIN. Despite the allocation, important preconditions for SBI routine seemed frequent exposure of this topic in media and guidelines, SBI facilitating information systems, and having SBI in protocol-led care. Hence, the second order analysis revealed that the applied implementation strategies have high potential on the micro professional level and meso-organisational level, however due to influences from the macro- level such as societal and political culture the effects risks to get nullified.

Conclusions: Essential determinants perceived for the implementation of SBI routines were identified, in particular for training and support and financial reimbursement. However, focusing only on the primary health care setting seems insufficient and a more integrated SBI culture, together with meso- and macro-focused implementation process is requested.

Background

Alcohol consumption is a substantial contributor to the global burden of disease. It is a leading factor for more than 200 diseases, injuries and other health conditions with ICD-10 codes.¹ The highest levels of alcohol consumption can be found in the European Union with approximately eleven litres alcohol per capita per year.¹ Evidence shows that 20-30% of patients who present in primary healthcare are risky drinkers.² Several meta-analyses have shown that simple screening consisting of a few standardised questions, followed by a brief counselling intervention (consisting of simple advice or psychological counselling) significantly reduces alcohol consumption in primary healthcare populations.³⁻⁶ However, there is a large gap between patients' needs and the actual provision of advice. In current European primary healthcare settings^{7,8} less than 10% of the population at risk are identified, and less than 5% of those who could benefit are offered screening and brief advice. Furthermore, alcohol is the least discussed lifestyle theme compared to smoking, physical activity and dietary habits in Dutch primary healthcare.⁹

Barriers for screening and brief intervention (SBI) delivery by primary healthcare professionals have been identified in previous research and primarily comprised lack of knowledge in health providers; lack of adequate resources and support; and, time constraints in terms of perceived workload for SBI.¹⁰⁻¹²

An increasing number of studies are being conducted in primary healthcare to stimulate the uptake of SBI for risky alcohol consumption (i.e. implementation strategies)^{2,13,14}, albeit with very limited success. The effectiveness of these so-called implementation strategies are summarised in several reviews.¹⁵⁻¹⁷ In short, these reviews found that effectiveness of implementation programmes on SBI delivery increases when they are multi-component¹⁵, contain higher intensity effort¹⁶, and focus on GP's and mid-level professionals simultaneously.¹⁷ These enablers of improvements are known as determinants of practice. The detailed process of these enablers in reaching actual uptake of SBI for risky alcohol consumption, are described in mechanisms of change.¹⁸ More insight into determinants and actual mechanisms of change would help to tailor implementation programmes to key issues.¹⁸ There are several qualitative studies conducted on barriers and facilitators for SBI delivery (e.g.¹⁹⁻²¹), although these give limited empirical insight into determinants of practice and mechanisms of change while implementing SBI in daily practice. This qualitative study was conducted after a controlled randomised trial to provide more insight into the factors and mechanisms of SBI implementation for risky alcohol consumption in primary healthcare. Linking theoretical knowledge from the implementation science database to practice-led experiences, views and attitudes from primary health care providers would add important knowledge on the current implementation gap. Therefore, the purpose of this qualitative study is to explore according to professionals' views on *why*,

how, for whom and under what circumstances implementation strategies worked or did not work in increasing SBI.

Methods

Study design

We conducted a qualitative study with realist evaluation as methodological orientation after the Optimising Delivery of Healthcare Interventions (ODHIN) randomised controlled trial.²² The ODHIN study attempted to overcome barriers for primary health care professional change by testing three different implementation strategies in a cluster randomised factorial trial in five European countries that represent the European alcohol levels (England, Catalonia, Sweden, Poland and the Netherlands). These countries differed in their organisation of primary care and their drinking patterns so the precise content of the implementation strategies were fine-tuned to country contexts. With regard to the lack of knowledge in healthcare professionals, we applied a training and support (T&S) implementation programme. In this programme the professionals' role security and therapeutic commitment were taken into account in order to address issues during training and support. The programme consisted of two initial 1-2 hours face-to-face educational trainings, and one (10-30 minutes) telephone support call. With regard to lack of resources and support, we applied country-dependent financial reimbursement (FR) schemes. FR concerned payment for screening and advice activities, with rates based on existing country-specific financial reimbursement for clinical preventive activities. Finally, perceived workload was addressed by an internet-based method of delivering advice (e-BI) instead of face-to-face brief interventions to save professionals' time.²² In the trial, these strategies were tested in every possible combination and resulted consequently in eight allocation groups. The perspective of the Realist Evaluation^{23,24} is an approach that originates from educational research. The core of this approach were the 'how' and 'why' questions²³, which fitted our research question of evaluating the implementation strategies applied in the ODHIN study. From this perspective, we sought to establish what worked, for whom, in what circumstances, in what respect, to what extent, and why. Our focus thereby was on the processes by which the ODHIN trial achieved its outcomes. Its starting point was that it was not only the implementation strategy that changed professional behaviours or processes, but also the participants' reaction to the opportunities provided by the programme that triggered the change, in combination with reinforcing or hindering factors outside the programme.²³

The consolidated criteria for reporting qualitative research (COREQ-32)²³ were used to design and report the current study.

Ethics approval for the study was obtained from the relevant approval bodies within each country: In Catalonia, the Clinical Research Ethics Committee of the Jordi Gol I Gurina Primary Health Care Research Institute and from the Clinical Research Ethics

Committee of Hospital Clínic de Barcelona; in Poland, Resolution No. KB- 0012/105/11 adopted by the Commission of Bioethics of the Pomeranian Medical University in Szczecin; and, in Sweden by the: Regional Ethical Review Board in Göteborg, reference number: 658/12, with approval granted for both sites in Göteborg and Linköping. In the Netherlands, the Committee on Research inv. Human Subjects (CMO) ethical board declared that no ethical approval was required in the Netherlands. In all four countries, all participating health care providers signed a written informed consent and the interviews did not place burdens on the participants.

Framework analysis

The ‘Tailored Implementation for Chronic Diseases’ framework (TICD)¹⁸ was used in applying framework analysis. The TICD framework was primarily developed to implement changes in prevention and chronic disease management in primary healthcare, and is through a systematic review and consensus process based on an integrative analysis of 14 previously published frameworks, theories and models. The framework includes seven domains of implementation determinants: 1) guideline factors; 2) individual health professional factors; 3) patient factors; 4) professional interactions; 5) incentives and resources; 6) capacity for organisational change; 7) social, political and legal factors. The framework is designed to understand change of professional behaviour and organisation of practice¹⁸ and was applied as an organising principle. Consequently, the framework was relevant in this more structured approach to qualitative data analysis, in order to build on previous body of research in barriers for implementation of evidence-based practice. Besides, it provides room to add concepts, other than already existing in the framework. This flexibility was relevant in facilitating the ‘open’ nature of the topic guide, which is provided below.

Participants and setting

Of the five trial countries, only England was not able to participate due to lack of funding. From the 96 participating Catalan, Swedish, Polish and Dutch primary healthcare units (PHCU), each country research team invited ODHIN participating professionals to participate to the qualitative study. Four of the five trial countries received funding for this qualitative study. From the 96 participating Catalan, Swedish, Polish and Dutch primary healthcare units (PHCU), each country research team invited professionals to participate. The recruitment of individuals was based on purposive sampling throughout a range of maximum variation, to receive insight into why, how, for whom and under what circumstances the implementation strategies work. The sampling was based on three features:

1. occupation: GP or nurse, although in Poland only GPs were invited as no nurses participated in the trial²²

2. screening performance after receiving implementation strategies: professionals with upper quartile versus lowest quartile of country screening rates. The screening rate was calculated as the number of completed screens divided by the total number of consultations of all patients eligible for screening.
3. implementation strategy: T&S versus no T&S. The T&S group includes professionals from 4 allocation groups: T&S alone, T&S + FR, T&S +e-BI and T&S + FR +e-BI. The non-T&S group includes professionals from the other four allocation groups: FR alone, e-BI alone, FR + e-BI, and no strategy. This sampling criterion ensured that professionals who received these different types of strategies were equally included in our study sample.

Professionals were invited by mail and by telephone. In case of non-response after email, we invited professionals directly by phone and planned the interviews.

Data collection

Interviews were performed between February and July 2014 by ODHIN trial researchers and focused on all three implementation strategies. Furthermore, field notes were made during and after the interviews. Researchers in different countries varied somewhat in posing their questions about the three strategies. Sweden and the Netherlands pro-actively asked professionals about experiences with all three implementation strategies. Catalonia covered all three but focused on T&S, whereas Poland mainly focused on the project generally and asked for further explanation when any of the strategies was raised by the professionals themselves.

We conducted semi-structured individual interviews by telephone using interview guides and topic lists developed for this study. No other people were present at the time of the interviews, these were conducted in private rooms. Topic lists were piloted and revised according to the results of the first interviews in each of the countries. Both the realist evaluation perspective and TICD framework served as a guide in developing the topic list (the interview guide is available on request):

Why?

- Engagement: reasons for subscribing to the ODHIN trial

How and for whom?

- Description of the SBI implementation process: description of SBI proceedings and expectations

Under what circumstances?

- Barriers and facilitators to following the guidelines on risky alcohol consumption
- Facilitators or barriers to implementing SBI, related to the allocation groups
- Opinions and suggestions for organizational and political barriers and facilitators
- Other thoughts and suggestions to speed up the implementation process

All interviews were audio taped, transcribed verbatim in each country's native language and anonymised.

Data analysis

The analysis consisted of four phases. First, each country coded independently - at least two researchers from each country independently coded fragments of the transcripts inductively and with constant discussion on interpretations, into English codes to facilitate building an international code book.²⁶ In this way, country researchers discussed on national and on international level their interpretation of the interviews, exchanged their views and came to an agreement for the appropriate code for the international code book. This final code book covered national as well as international interpretations, which allowed codes applied in single countries. Data collection and data analyses were alternated. Creditability was addressed by checking findings from analysis by further interviews. Furthermore, the research team included general practitioners and nurses as well. Each country used software and methods that they were familiar with, i.e. Atlas.ti version 7.1.5 (ATLAS.ti Scientific Software Development Company, GmbH, Berlin, Germany), Nvivo 10 or Microsoft Word to facilitate the coding process. Codes were structured by the seven broad TICD framework domains¹⁸, followed by an open coding procedure, resulting in a largely inductive content analysis. When codes could not be structured by one of the seven TICD domains, they were organised in an eighth additional domain, based on appropriateness of the data.

Second, to minimize country differences in interpretations of same data, all emerging codes were classified in one Excel file code book and discussed by all researchers during face-to-face meetings, conference calls, and electronic mail correspondence. The research group agreed on the English translation of the developed codes to ensure codebook fidelity. Data collection proceeded until achievement of conceptual saturation on country level, which we defined as a state in which no new themes or codes could be generated.²⁶ Analyses were conducted by each country research team with the described internationally agreed format, which made it possible to perform meaningful analysis with large numbers of interviews.

Third, to maximize discussions of interpretations, exchange of views and reach of agreements, the affinity diagram method²⁷ was applied as an instrument in face-to-face meetings to achieve final international consensus in the research group about grouping codes and defining themes. Whereas Realist Evaluation and TICD were used as perspectives for interpretation of data, diagram affinity method was applied as an instrument to achieve consensus in analysis, as recommended in multinational qualitative research.²⁷

Fourth, resulting themes from the affinity diagram method were linked to the existing TICD framework domains. The general analyses were based on the themes from the third phase that had emerged nationally and internationally. To reach in-depth analyses level, the TICD concepts were not only described as domains separately, but as a second-order analysis we also explored the relations between the TICD concepts in

order to catch the complexity of multinational implementation.²⁸ The Dutch researchers coordinated the analyses, which were subsequently evaluated and discussed by the partner researchers.

Results

Study population

Of the 138 professionals invited, 68 participated including 40 GPs and 28 nurses (mean response rate 49%). The main reasons for not participating were lack of time and unanswered calls of the research team. Participant study and demographic characteristics were shown in table 1. Participating professionals were mainly female with a mean age of 47. Catalonia needed the highest number of interviews to achieve data saturation and Poland had the lowest number of interviews, primarily because no nurses participated in the trial. Participants roughly evenly represented the three purposive sampling domains of occupation, screening performances and implementation strategy.

Table 1. Participating professional profiles

	Catalonia	Sweden	Poland	Netherlands	Total
N GPs	12	5	12	11	40
N nurses	10	10	0	8	28
N high performance	13	9	6	10	38
N low performance	9	6	6	9	30
N T&S	11	5	6	9	31
N no T&S	11	10	6	10	37
N FR	13	5	7	10	35
N no FR	9	10	5	9	33
N e-BI	9	6	3	11	29
N no e-BI	13	9	9	8	39
Male (%)	27	13	16	37	26
Mean age	47	52	47	44	47
Total	22	15	12	19	68

Barriers and facilitators to implementation

Table 2 links already existing theoretical TICD concepts with practice-led affinity diagram themes that rose from the data analyses. In more detail, there are seven TICD domains¹⁸ that included 39 relevant concepts in light of our findings, being reflected in the two left-hand columns of the table. The two right-hand column include 57 affinity diagram themes that derived from the grouped coded data. Thereby this table links theory and practice and consequently gives insight into important determinants for practice within this population of health professionals. An eighth additional concept was added that did not fit within the original TICD framework and was related to 'Implementation strategy practicalities'.

Table 2. T1CD domains and concepts linked to Affinity Diagram themes and codes

T1CD Domain	Theory-led T1CD concepts	Empirically-led Affinity Diagram themes	Codes
1.Guideline factors	Cultural appropriateness	<ul style="list-style-type: none"> CULTURAL APPROPRIATENESS 	SBI is not a task for PHCU_referral to specialized care outside the PHCU; no guideline available_SBI too late
	Strength of recommendation	<ul style="list-style-type: none"> BARRIERS TO ADHERE TO THE GUIDELINE 	Too strict_nr of drinks; SBI does not fit in short time consult; doubts about effectiveness pro-active screening
	Compatibility	<ul style="list-style-type: none"> ADHERENCE TO GUIDELINE ROUTINE FOLLOW-UP OF SBI 	Return to the habitual system; routine_Application of the screening in all cases; already a routine; routine_preventive activities; SBI part of the nurse's protocol; SBI part of GP's protocol/routine; follow-up after SBI suboptimal; policies_screening during initial general interview with every new patient; focus on alcohol addicted patients/co-addicts; focus on chronically ill patients; routine_follow-up of patients; repeat SBI
	Observability	<ul style="list-style-type: none"> FACILITATORS TO ADHERE TO THE GUIDELINE 	Partly adherence to guideline; adherence to guideline; clear cut-off screening tool stimulates brief intervention; use evidence based knowledge/material - mi; adherence implementation takes a while; adherence_initial difficulties; adherence_simple adaptation process; interventions were feasible; feasibility_of the instrument
2.Individual factors	Feasibility	<ul style="list-style-type: none"> ADHERENCE TO GUIDELINE FACILITATORS TO ADHERE TO THE GUIDELINE IMPLEMENTATION OF GUIDELINES FEASIBLE GUIDELINES 	Example of interventions
	Agreement with recommendation	<ul style="list-style-type: none"> EVALUATING OWN PERFORMANCE IMPLEMENTING NEW PRACTICE ROLE PERCEPTION SCREENING OPPORTUNITIES BARRIERS 	Screen to make patients aware of daily drinking habit; role perception_patient motivated when given BI from a GP; performance perception_effects of SBI; performance perception_no effects of SBI; my role to start the process; role perception SBI; barrier screening_perceived_not relevant in context; role perception to recognize signs given by a patient; it's not my role; agreement recommendation; awareness_alcohol is not a medical problem
	Expected outcomes	<ul style="list-style-type: none"> PERSONAL MOTIVATION TO PARTICIPATE FROM SOCIETAL PERSPECTIVE COLLABORATION FROM INDIVIDUAL PERSPECTIVE EVALUATING OWN 	ODHIN_outcome expectation_to catch more case positives; role perception_patients like GPs to ask about lifestyle; expectation_patient's reaction; expectation_conformed to expectations; professional age; motivation to participate ODHIN_curiosity about the outcomes; expected MI intervention outcome_high; expected intervention outcome_low; expectation_With no initial expectations;

TICD Domain	Theory-led TICD concepts	Empirically-led Affinity Diagram themes	Codes
		PERFORMANCE • ROLE PERCEPTION • PROFESSIONAL'S EXPECTATIONS • I DON'T CARE • BARRIERS	lack of motivation to change; barriers referral_big step; GP afraid of patient's reaction
	Emotions	• IMPLEMENTING NEW PRACTICE • BARRIERS	E-health_using e-health is a personal weakness; new patient; hard to screen GP's own friends or acquaintances
	Frustration	• IMPLEMENTING NEW PRACTICE	ODHIN impact_more frustration
	Intention and motivation	• PERSONAL MOTIVATION TO PARTICIPATE FROM SOCIETAL PERSPECTIVE • TRAINING • COLLABORATION FROM INDIVIDUAL PERSPECTIVE • E-HEALTH • PERSONAL MOTIVATION • INDIVIDUAL PERSPECTIVE • I DON'T CARE • BARRIERS	Motivation to participate in ODHIN_to help patients; ODHIN training_positive but not fully attended; Motivation to participate ODHIN_motivation for intervention; motivation to participate ODHIN_easier with a size of alcohol problem; motivation to participate ODHIN_barrier referral; e-network; e-health_positive in e-health; e-health_barrier referral; e-health_no time to become familiar with e-health intervention; e-health_not familiar with website content; e-health_negative attitude; motivation to participate ODHIN_consider load and benefit; not motivated by financial incentives; motivation to participate ODHIN_to act pro-socially; motivation to participate ODHIN_personal interest/benefit; motivated by ODHIN financial incentives; motivation to participate ODHIN_negative; motivation to participate ODHIN_interesting subject; not motivated to improve SBI; low patient awareness_inhibits professional; low motivation to change_inhibits professional; motivation to change_motivates BI; patient reactions_denial inhibits brief intervention;
	Learning style	• TRAINING • IMPLEMENTING NEW PRACTICE • ROUTINES • SELF-EFFICACY	ODHIN training_increases awareness of the problem; ODHIN training_temporary stimulation; ODHIN training_positive; ODHIN presence cause reminders/awareness_temporary; continuous triggers necessary for SBI; routine and practice
	Self-efficacy		Self-efficacy in BI_high; high screening self-efficacy; self-efficacy; self-efficacy_frustration; self-efficacy in BI_moderate; performance perception_GP can always do something
	Awareness and familiarity with the recommendation	• PERSONAL MOTIVATION TO PARTICIPATE FROM SOCIETAL PERSPECTIVE	ODHIN motivates to screen pro-active; awareness of alcohol problems; importance of screening

TICD Domain	Theory-led TICD concepts	Empirically-led Affinity Diagram themes	Codes
	Knowledge	<ul style="list-style-type: none"> • TRAINING • IMPLEMENTING NEW PRACTICE • I DON'T CARE • BARRIERS • SCREENING OPPORTUNITIES 	Skills thank to previous training; ODHIN impact_encouragement to introduce more prevention; previous training_don't remember; barrier screening_language barrier; barrier_screening_information from system not available; barrier BI_skills; Skills_plurimedication; Patient nightlife related with drugs / alcohol; patient known to drink too much; screen because of patient signals; skills_professional knows well patient's medical history; importance_associated pathology; screened patients suspected of drinking alcohol; patient drunk during the visit; problem reported by family member
	Knowledge about own practice	<ul style="list-style-type: none"> • COLLABORATION FROM INDIVIDUAL PERSPECTIVE • I DON'T CARE • BARRIERS 	Barrier screening_already SBI by colleague; barrier screening_other important health and other topics; barrier screening_sociodemographics; patient religious issues
	Skills needed to adhere	<ul style="list-style-type: none"> • IMPLEMENTING NEW PRACTICE • PERSONAL MOTIVATION INDIVIDUAL PERSPECTIVE • PROFESSIONAL PATIENT APPROACH • PROFESSIONAL'S EXPECTATIONS • BARRIERS • SCREENING OPPORTUNITIES 	ODHIN impact_new skills/procedures; motivation to participate ODHIN_need for more knowledge and skills; expectation_increase knowledge/skills about interventions; skills_no judgemental attitude /tolerance; skills_professional keeps motivating the patient; skills_individual approach to patient; alcohol is a sensitive issue / difficult subject; need for more knowledge & skills for SBI; performance perception_screening justified by the research project
	Capacity to plan change	<ul style="list-style-type: none"> • PERSONAL MOTIVATION TO PARTICIPATE FROM SOCIETAL PERSPECTIVE • IMPLEMENTING NEW PRACTICE 	Barrier screening_economic crisis situation; ODHIN impact_introduction of new data into patients' records
	Nature of the behavior	<ul style="list-style-type: none"> • IMPLEMENTING NEW PRACTICE 	ODHIN impact_effort to perform
	Self monitoring or feedback	<ul style="list-style-type: none"> • PERSONAL MOTIVATION TO PARTICIPATE FROM SOCIETAL PERSPECTIVE • EVALUATING OWN PERFORMANCE • IMPLEMENTING NEW PRACTICE 	ODHIN_outcome_catching patients in early stage of disease and follow-up; motivation to participate ODHIN_awareness of trivializing; satisfaction with own performance; lack of satisfaction with own performance; self-monitoring of screening; self monitoring of BI; insight SBI potential afterwards; ODHIN impact_more patient/new groups of patients screened; ODHIN presence cause reminders/awareness_own consumption behavior; ODHIN presence cause reminders/awareness;

TICD Domain	Theory-led TICD concepts	Empirically-led Affinity Diagram themes	Codes
3.Patient factors		<ul style="list-style-type: none"> SCREENING OPPORTUNITIES I DON'T CARE BARRIERS 	ODHIN did not make any difference; ODHIN presence did not cause reflection on own consumption behavior; barrier screening_simplly forgotten; has routine; barrier screening_experienced workload; Patient age; patient gender; physical GP's tiredness; Screened every patient (or tried to screen)
	Patient behavior	<ul style="list-style-type: none"> PATIENT REACTIONS 	Patient reactions; feel suspected of being a drinker; afraid /suspicies; stressed /tense; not honest; honest; frustration; defensive; surprise; relief; no objection/acceptance; negotion/trivialization
	Patient beliefs and knowledge	<ul style="list-style-type: none"> PERCEIVED PATIENT AWARENESS LACK OF INTEREST IN E-BI 	Awareness_personal decision of the patients; awareness_self-control of drinking; patient reactions_awareness guidelines; BI_difficult when patients not aware; patient reactions_dont treat beer as alcohol; self-efficacy in BI_low / doubts if patiens will change anything; patient reactions_lack of interest e-health; patients not interested in e-BI
	Patient motivation	<ul style="list-style-type: none"> PATIENT TRUST REQUIRED MOTIVATION TO CHANGE 	SBI requires patient's trust; motivation to change_Serious alcohol problem; motivation to change_Social support
	Patient preferences	<ul style="list-style-type: none"> PATIENT REACTIONS 	Patient reactions_positive
	Communication and influence	<ul style="list-style-type: none"> DECISION TO PARTICIPATE GENERAL ASSESSMENT OF PHCU ROUTINES AND ENGAGEMENT 	Decision to participate in ODHIN_agreement; decision to participate in ODHIN_GP decided to participate; decision to participate in ODHIN_nurses agreed; decision to participate in ODHIN_practice nurses not involved; motivation to participate ODHIN_order or influence of other professional /supervisor/ colleague, etc.; GP takes the lead in ODHIN SBI; engaged other staff in alcohol discussions than those involved in the Odhin project; team (not) on the same line; different routines among the staff
	Referral processes	<ul style="list-style-type: none"> BARRIERS TASK DIVISION IN THE TEAM REFERRAL 	Addiction care disappointing; GP internal referral to specialized professional; nurse referral to other(s); ODHIN initiates referral option specialized nurse; GP referral to addiction care; need for low barrier referral possibilities; conditions in the PHCU_additional support
4.Professional interactions	Team processes	<ul style="list-style-type: none"> BARRIERS ORGANISATION OF SBI CARE TASK DIVISION IN THE TEAM LEARNING FROM EACH OTHER MAKING AGREEMENT WITHIN THE PRACTICE 	Recent screening; colleagues less practice/experience; organize care multidisciplinary; counseling done by other profession; care requires a specialized practice nurse; team process SBI_SBI only partly by nurse; unknown patient; practice nurses_have more time_for MI; other professionals have more time; practice SBI in team; share experiences; lack of communication; sufficient communication; nurse not informed about procedures; agree on team objectives; agree on SBI strategy

TICD Domain	Theory-led TICD concepts	Empirically-led Affinity Diagram themes	Codes
5.Incentives and resources	Undefined	<ul style="list-style-type: none"> • DIFFERENCE IN OPINIONS 	ODHIN_waisted money
	Availability of necessary resources	<ul style="list-style-type: none"> • PHYSICAL WORKING CONDITIONS IN THE PHCU • DIFFERENCE IN OPINIONS • TOOLS AS FACILITATORS • SCREENING TOOL USEFULNESS • TRIGGER FOR SCREENING • IMPORTANCE OF TIME 	Conditions in the PHCU_privacy; conditions in the PHCU_disturbances; ODHIN did not lack resources; little bureaucracy; ODHIN provides tool for BI; need for patient information_low barrier patient information; more resources in the treatment of the patient; screening instrument not within reach; advice_use available training and tools; screening tool helps to structure; advice_use screening tool; ODHIN provides screening tool; screening instrument Suitable instrument; screening tool did not help; screening instrument_too complicated for patients; screening instrument_easy to use; screening instrument_anonymous; visible screening instrument does not stimulate; visible screening instrument stimulates; need for summary card on desk; advice_time is necessary resource; GPs want more time per patient; increase available time for extra practice nurses; time pressure inhibits BI; time pressure inhibits GP's MI; time pressure inhibits screening; time is no barrier to screen; time is no barrier for advice; addicted patients need more time; time for creating right atmosphere; time pressure forces need for follow-up appointment
	Continuing education system	<ul style="list-style-type: none"> • IMPORTANCE OF TRAINING 	Advice_continuous training; training should be organized in PHCU; more role playing; Providing training tools suitable for professionals
	Financial incentives and disincentives	<ul style="list-style-type: none"> • IMPORTANCE OF FINANCES 	No financial resources from health Insurance; finances required for practice nurse; financial incentives rewards your effort; financial incentives would create more priorities; more funds needed
6.Capacity for organisational change	Information system	<ul style="list-style-type: none"> • ROLE IN INFORMATION SYSTEM 	Usual registration in information system; information system obligatory field; no use of information system; register SBI in information system; information system not adapted to SBI; information system not obligatory field
	Assistance for organizational changes	<ul style="list-style-type: none"> • PHCU SBI POLICY 	Advice_invite a consultant; practice nurse not skilled
	Monitoring and feedback	<ul style="list-style-type: none"> • NURSES PROTOCOL FOR SBI 	
	Priority of necessary changes	<ul style="list-style-type: none"> • PHCU SBI POLICY 	Need for ongoing evaluations Advice_SBI prioritization
7.Social, political, legal	Regulations, rules, policies	<ul style="list-style-type: none"> • SYSTEMATIZATION OF SBI • PHCU SBI POLICY • NURSES PROTOCOL FOR SBI 	Policies_need for a systematic approach to disease prevention; make it part of protocol; make it part of performance indicators; Nurses protocol adapted in line with ODHIN
	Economic constraints on the healthcare budget	<ul style="list-style-type: none"> • INCREASE PUBLIC AWARENESS 	Advice for improving public health_society should be richer

TICD Domain	Theory-led TICD concepts	Empirically-led Affinity Diagram themes	Codes
factors	Influential people	<ul style="list-style-type: none"> • IMPORTANCE OF REGIONAL POLICY • INCREASE PUBLIC AWARENESS • AWARENESS OF PREVENTION TASK OF PRIMARY CARE 	The board plays an important role; advice_increase public awareness (media); advice_increase public awareness (media)_broad lifestyle; advice_increase public awareness (media)_involve environment; advice_increase school and parent awareness; little effect public campaigns; synergy effect of advice from multiple people; less ads; change social attitudes; advice_increase primary care awareness outside PHCU; increase awareness in professionals; prevention task of PHCU
	Legislation	<ul style="list-style-type: none"> • NEED FOR EFFECTIVE POLICY ACTIONS • MORE STRICT LEGISLATION 	Mandatory trainings for GPs; advice_increase alcohol taxes_not effective; advice_increase alcohol taxes; advice_legislate higher age buying alcohol; advice_make alcohol less available; fear of bureaucracy
	Payer or funder policies	<ul style="list-style-type: none"> • INCREASE PUBLIC AWARENESS 	Advice for improving public health_don't waist public money on projects like ODHIN
	Undefined	<ul style="list-style-type: none"> • INCREASE PUBLIC AWARENESS • NEED FOR EFFECTIVE POLICY ACTIONS • AWARENESS OF PREVENTION TASK OF PRIMARY CARE 	Advice for improving public health_use disulfiram implants; advice for improving public health_state alcohol policy is schizophrenic; raise awareness of screening, BI and available tools; build trust between GPs and patients; advice_organize peer buddy's; increase knowledge in primary care professionals; Approach general/integral; policies_screening during initial general interview with every new patient; introduce more programs like ODHIN
	TRAINING AND SUPPORT		Caused awareness; MI requires long term practice; MI useful for other lifestyle issues; positive; preference for more factual knowledge; role playing_not favorable; temporary stimulus
8.Implementation strategy practicalities	FINANCIAL REIMBURSEMENT		No effect; extra motivation
	E-HEALTH		low outcome expectation; low patient motivation inhibits professional; easily accessible intervention; Increases awareness; negative attitude; no time to become familiar with e-health; not applicable for elderly; not applicable for low SES; no effect

As presented in table 2, most affinity diagram extracted themes fit the ‘individual factors’ TICD domain. Also, the TICD domains ‘professional interactions’ and ‘incentives and resources’ were important in gaining insight into the mechanisms behind the allocations. The importance of the TICD domains ‘guideline factors’, ‘patient factors’, ‘capacity for organizational change’ and ‘social, political and legal factors’ in explaining the processes of the allocations, varied per allocation. High as well as low performer views equally covered the TICD domains, whereas GPs and nurses differed in covering TICD domains. GPs held clearer views than nurses on healthcare system barriers and facilitators, which resulted in the TICD domains ‘capacity for organisational change’ and ‘social, political and legal factors’ being mainly covered from the viewpoint of GPs.

Why?

Many professionals, both high and low screening performers and both nurses and GPs, had a positive role perception with regard to conducting SBI. Most professionals participated because of their awareness of the prevalence of alcohol-related problems and the willingness to contribute to the prevention of risky drinking. For most professionals also the likelihood of being allocated to T&S was an important motive for participation.

Alcohol problems are really big in this area. I've been observing them for years.(GP, FR, low performance, PL)

Polish and Catalan GPs reported the additional value of FR besides their willingness to contribute to the prevention of risky drinking. Dutch and Swedish GPs as well as some Catalan nurses reported not being motivated to participate for a financial reimbursement, whereas Polish and Catalan GPs felt positive about providing good care and getting paid for it as well.

There were no professionals who mentioned any e-BI related motivation to participate in the trial. Most professionals, GPs as well as nurses, were ambivalent in their attitude towards e-health. The professionals who were positive about the e-BI concept primarily thought it was useful in information provision for patients.

How and for whom?

Aspects in three TICD domains appeared to be relevant in answering the question *how* and *for whom* T&S worked: *guideline factors*, *individual factors* and factors related to *incentives and resources*. Facilitating T&S ingredients for high SBI performance can be summarised into knowledge gained, application of tools, support offered by the trainer, and team-based education. Professionals who received training and support indicated factors that would make training and support even more effective, i.e. continuous training provision, more time to learn intervention techniques and more tailoring to experienced barriers, such as a perceived lack of time for conducting SBI. In Catalonia,

Sweden and the Netherlands, training and support further raised awareness of the guidelines and stimulated many of the professionals to keep using them. Primarily for high performing GPs, training and support provided assistance in SBI application in daily practice. Most of the training and support allocated professionals perceived the guidelines to be feasible and compatible with daily practice. Most professionals in the ODHIN study wanted to know and to become skilled in *how* to implement and conduct SBI rather than be convinced of the *importance* of implementing:

“During my education there was some attention paid to motivational interviewing, but this training was very welcome as it cleared things up, such as fine-tuning my patient approach to their phase of behaviour change according to the behaviour change matrix.” (Nurse, T&S, high performance, NL)

High performing professionals reported that they gave more priority to SBI in their routines than before ODHIN. After attending training and support sessions, professionals felt that it was not only a matter of having time, it was also a matter of prioritising. They found that it was actually possible to frequently ask patients about alcohol consumption, even during high workload:

“The more often you ask the questions, it will become more of a routine, it takes time to incorporate new procedures and ask the questions, but most of the time you can ask these questions during each visit” (Nurse, T&S, high performance, SWE)

“You have to decide beforehand whether you want to reserve time for this. Do we think it’s important enough to spend time on?” (GP, T&S+FR+e-BI, high performance, NL)

Furthermore, learning how to raise the ‘alcohol topic’ in patient groups with varying motivation to change was appreciated in the training and support sessions. Some high performing professionals used study participation to start the conversation and to make the topic more easily accessible:

“I stated: “We are taking part in a project aimed at people’s wellbeing”” (GP, T&S+FR, high performance, PL)

The high performing professionals who attended training and support, reported being stimulated in discussing SBI experiences within their team. This facilitated a team approach in doing SBI:

“We could have talked about this without the ODHIN project. But it gave us a reason to sit down and do so.” (GP, T&S, high performance, SWE)

Furthermore, many professionals already knew about the existence of SBI tools. Even so, they were additionally informed during T&S where to find the right tools and how to apply them appropriately.

However, both low and high performing professionals reported that training and support were felt to be a temporary stimulus, and that alcohol is just one of the many important themes to discuss. Embedding SBI in the long term requires a continuous trigger, such as booster sessions. This also facilitates prioritising:

“The emphasis on your work is on what you are currently busy with. It would be the same if I had participated in a study about cardiovascular diseases.”

(GP, T&S+FR+e-BI, high performance, NL)

TICD domains *individual factors*, factors related to *incentives and resources* and *social, political and legal factors* were of relevance in evaluating *how and for whom* a financial reimbursement strategy would work. Financial reimbursement seemed to differ in impact between Poland and Catalonia compared to Sweden and the Netherlands, mainly due to low personnel levels and salary levels.

“Because with the cutbacks there are fewer of us and we have to...stand in for people and that’s hard, isn’t it?” (GP, T&S+FR, high performance, CAT)

“Getting an incentive is always good. If this is financial or economic, I think it could be good, but I am not completely sure about it. When you get invited to participate in a study they ask you “Do you want to participate?” and you take part voluntarily. In the end, it turns out that someone publishes an article and your name is there, that’s okay. Of course both the financial and professional incentives are important, but with the financial one you feel they treated you well.” (Nurse, T&S+FR, high performance, CAT)

Views of Swedish and Dutch professionals allocated to financial reimbursement did not differ between high and low performers and those not being allocated to financial reimbursement. Swedish and Dutch professionals thought it was important to get paid for the care provided, but they perceived it as inferior to being a good care provider:

“Now it is the diagnosis that brings in money, nothing out of this really benefits the patients, but that’s something for financially educated managers to calculate and put in charts and to perform some kind of statistics. What is important in healthcare is the patient.” (GP, T&S, low performance, SWE)

Furthermore, in the ODHIN study the financial reimbursement scheme differed per country. In Poland and Catalonia, professionals were reimbursed directly, whereas in Sweden and the Netherlands reimbursement was applied on PHCU level. In Sweden and the Netherlands, professionals reported that financial resources in principle were of high importance. However, both high and low performers from these countries preferred being structurally paid for their preventive services by health insurance, rather than a temporary project based payment. They considered increased resources from health insurances required for long-term improvement of SBI:

"I have to pay my practice nurse. If I can only pay her for other tasks [other than asking for alcohol consumption], I have to pay for it myself when she is going to ask about alcohol consumption." (GP, T&S+e-BI, low performance, NL)

It turned out that for all four countries patients' lack of interest inhibited both nurses and GPs from being active in referring patients to e-BI. It neither facilitated nor guided them in providing brief interventions, as patient reactions were frequently not very promising. Therefore, face-to-face interventions were the preferred method in such cases. Consequently, the high performers did not give any e-BI related explanations for their performance levels, whereas the low performers explained the non-facilitating role of e-BI.

"Well, I gave them the e-BI tool and asked them to access it. However, it is up to them, you can ask them to do it, but they don't always do so. It happens very often, your role as a professional is to say 'look, if you want more information here it is' but in my opinion this is a challenging thing." (Nurse, T&S+FR+e-BI, high performance, CAT)

"If they didn't have a computer at home, or if they did not feel comfortable using one - then it was really not any use to recommend it to them. It was meant for those who felt that they wanted it... I don't know if they visited the website or not.. I have no idea..." (Nurse, e-BI, low performance, SWE)

Under what circumstances?

The fact that many health professionals throughout the four countries participated in a trial concerning preventive services for risky alcohol consumption, raised their awareness and frequency of providing these services. That means that just putting this theme as item on the agenda already makes the professional more active in SBI, irrespective of their allocation. This was illustrated by a professional who had not received any of the implementation strategies but was still a high performer.

"I know that before ODHIN I did not pay as much attention to this as after ODHIN. I did not have specific barriers for asking about alcohol consumption, but if you participate in this kind of project it will become more part of your automatism in anamnesis. (GP, no strategy, high performance, NL)

Consequently, before being able to receive a state of SBI routine, one should be increasingly aware of their SBI activities. Referral opportunities could provide stimulating thoughts for professionals to take up this activity. Another important precondition to make it part of a routine, is to include it in protocols and to set reminders.

“Include it in your protocol. Every time you see it [on your screen], you will be reminded.” (Nurse, T&S+FR+e-BI, high performance, NL)

However, there are some preconditions that can facilitate or hinder successful a implementation of brief interventions, such as information systems. As countries differed in their information systems, the role of the information system as a facilitator varied.

“Yes... it has facilitated our work a lot because we already had it implemented in our computerised medical record (E -CAP)... and ... and this is the usual computerized tool that we always use, as a result of this it has been much easier” (GP, T&S+FR+e-BI, High performance, CAT)

“I do register, but it's a bit difficult as we do not have an appropriate ICPC [declaration] code” (GP, FR+e-BI, low performance, NL)

Subsequently, professionals frequently reported high workloads, which caused T&S not to be sufficient to increase performance.

There are not enough GPs ... more time and more funds should be reserved ... e.g. one extra hour per week for preventive visits should be founded by the National Health Fund (GP, T&S, low performance, PL)

Another inhibiting factor was that the alcohol subject seemed to compete with other lifestyle prevention themes. For example alcohol received less media attention compared to other lifestyle prevention themes:

“For professionals, you have to notice it more, read about it more, pay more attention to it in the media and literature. (...) The lobby for quitting smoking is much bigger than the lobby for drinking less.” (GP, FR+e-BI, low performance, NL)

Second-order analysis: relations between framework domains

Many drivers for the trialled SBI implementation strategies were found in the TICD domains ‘Individual health professional factors’ and ‘incentives and resources’. However, these were embedded in other TICD domains to influence SBI implementation in daily practice. In particular, political culture - part of ‘social, political and legal factors’ domain - is such an important contextual factor that exert the SBI implementation in daily practice. To create an environmental SBI culture, a facilitating political and social culture is essential:

“The state earns most on alcohol and tobacco. So limiting consumption is against its economic interests.” (GP, T&S+FR, high performance, PL)

“There is a social acceptance for drinking.” (GP, T&S+FR, high performance, PL)

Furthermore, the organisational environment challenges the SBI implementation, even when implementation strategies seem to work at the individual level i.e.:

“The system of work should be changed. Besides alcohol interventions, interventions on nicotine, obesity, physical activity should be conducted. And I have 10-15 minutes per patient.” (GP, no strategy, low performance, PL)

“I do register [SBI], but it's a bit difficult as we do not have a good ICPC code [for health insurance declaration].” (GP, T&S+FR+e-BI, high performance, NL)

Implicitly, responses of both nurses and GPs show their perceived responsibility in SBI, yet as part of the SBI responsibility as society together. Despite their intrinsic motivation to prevent patients from alcohol-related disabilities, GPs and nurses feel more rationale for selective screening rather than opportunistic screening:

“When there are analytical alterations or when there's a sonogram that shows something, when there's a pathology behind it (...), it's easier to focus on it.” (nurse, FR, low performance, CAT)

These insights taken cumulatively, it seems that implementation strategies should be applied in other health care settings as well, next to primary health care. The ODHIN study tested implementation strategies at micro-level and meso-level. Implementation determinants on the macro-level as described by TICD domains seemed to challenge the tested implementation strategy influences. Therefore it raises the need for an integrative SBI approach to take broader than primary health care.

Discussion

The aim of this study was to explore, according to professionals' opinions, *why, how, for whom* and *under what circumstances* the implementation strategies tested in ODHIN increased or did not increase SBI. T&S improved knowledge and skills in team-based approach and taught professionals to prioritise SBI. Continuous provision, sufficient time for learning intervention techniques and tailoring to individual experienced barriers, were important perceived facilitators. Catalan and Polish professionals perceived financial reimbursement to be an additional stimulating factor, as SBI rates were smoothened by personnel levels and salary levels. Structural payment for preventive services, rather than a temporary project based payment, might have further increased the SBI-rates. Implementing e-BI seem to require more guidance than was delivered in ODHIN, for example in connection with unmotivated patients. Other preconditions for SBI care, irrespective of the allocation, are frequent exposure of this topic in media and guidelines; information systems that facilitate SBI (e.g. screening programmes); and having SBI in protocol-led care. However, despite having identified facilitating factors on the micro-individual level, the macro-level in which SBI is augmented to be implemented includes important barriers. These were mainly related to politics and social culture.

The purposive sampling strategy in this study was based on occupation, implementation strategy and screening performances. This qualitative study showed that allocation to T&S or FR influenced professionals' views, whereas e-BI did not seem to make any difference. Occupation did not seem to influence views, perceptions and opinions, although GPs reported higher importance of financial resources and experienced barriers in implementing routine SBI. Furthermore, GPs had clearer views on the barriers and facilitators of the healthcare system, which we perceive a result of different tasks and functions by professionals in the organisation of primary healthcare. Tailored strategies seem important, also with regard to who makes decisions and who is financially responsible. Furthermore, despite positive SBI outcomes after T&S and FR during high workloads, time constraints remained. This indicated the need for more profound changes in the structure of the healthcare organisation to facilitate further SBI improvements in primary healthcare.

In line with the literature, our study confirms that very few professionals used e-health in patient care.^{29,30} An important barrier for implementing e-BI was that professionals from all countries were mixed in their trust in e-BI in principle and they noticed that their patient population was not interested in e-BI. Despite the effectiveness of SBI self-help via internet in principle³¹, our findings imply that more efforts might be required in getting the facilitated e-BI access embedded into daily primary healthcare practice. For example, professionals seem to require clearer guidance in how the facilitated access can decrease their workload by using e-BI interventions that have proved to be effective.^{29,32} In the ODHIN programme offering e-BI might have been too much a matter of being 'dropped' as a strategy rather than personal guidance in using it with a population who is less familiar with the internet, such as the elderly or in a population with a low motivation to change alcohol consumption, as experienced during ODHIN.

When implementing lifestyle interventions such as alcohol related screening and brief interventions, it is important to address sustainable funding of services.³³ In the United Kingdom (UK), the Quality and Outcomes Framework (QOF) is a reimbursement scheme in which payment is based on fee-for-service and capitation systems rather than related to quality of care.³⁴ After 20 systematic reviews and one systematic reviews of systematic reviews³⁵, it is clear that pay for performance can be effective. However, policy makers should be warned that effects may be only realised on short-term and may be not as large as one may wish.³⁵ Pay for performance has potential, but it is not a "magic bullet". To achieve sustainable changes, it needs to be combined with other quality improvement initiations.³⁵

Of the total 57 concepts included in the seven domain TICD checklist framework¹⁸, 39 concepts were covered in this study. Non-covered concepts were mainly associated with topics not relevant in the study context, such as corruption or political stability. For Poland specifically, it is no surprise that guideline topics were hardly covered, as

no official guidelines exist. Furthermore, one can imagine that healthcare professionals talk more easily about their daily practice than about topics that are more general and policy-related, such as topics with *social, political and legal factors*. These topics were more indirectly covered in the second-order analysis. Other professional disciplines such as managers and policy makers could add on the more meso- and macro-perspective. In addition, more context-related items should receive attention- e.g. Poland mainly has solo-practitioners (GPs) who are not able to refer to other providers in the practice, or differences in country-specific guidelines to adapt SBI procedures.

Only four themes identified in the analysis did not match with the TICD checklist. These four were either very specific, such as opinions regarding specific medicaments, or very generally formulated, such as with increasing public awareness. However, these were of minor importance in answering the research question.

There are caveats as well as strengths to mention. The interview questions about allocation experiences and views varied across participating countries. Sweden and the Netherlands pro-actively asked professionals about their experiences with all three implementation strategies. Catalonia covered all three but focused on T&S, whereas Poland mainly focused on the project generally and asked for further explanation when any of the strategies was raised by the professionals themselves. Despite this systematic difference, there were minor differences in FR and e-BI data saturation due to the equally represented allocations. The e-BI coverage in the results section is less compared to FR and T&S. Despite reaching data-saturation, the participating professionals did not share much e-BI related data. Consequently, this data limitation impedes to provide full answer on the research questions related to e-BI and therefore deserves further research. Another caveat is the selection of professionals who are likely to be more motivated to prevent alcohol problems, compared to the greater primary healthcare professional population. This could make the implementation strategies less powerful, and it could make the conditional circumstances described of greater importance.

A strength of the study was the use of different country contexts when striving after code homogenisation of emerging themes in light of the Realist Evaluation built international code book. The Realist Evaluation then helped to distinguish between a context and a mechanism.³³ For instance, there were differences in the state of the art regarding SBI implementation. Catalan, Swedish and Dutch professionals already paid (some) attention to lifestyle prevention themes including alcohol, while many Polish professionals did not pay any attention to alcohol SBI before participating in ODHIN, which is in line with the absence of a Polish national guideline. Other examples are differences in countries' cutbacks in personnel and salaries, policies and social progress towards SBI implementation differed, which made comparisons sometimes difficult. To increase meaningful analysis of the data on international level, we organised face-to-face discussions and conference calls to agree on scientific value of our findings over all

four countries. In addition, a major strength of the study is that the approach of the realist evaluation was combined with the TICD framework analysis. The Realist Evaluation perspective was developed to unpack the ‘how’ and ‘why’ questions and illuminate the many, varied and interdependent, mechanisms by which interventions may work (or fail to work) in different contexts in education.^{24,25} This makes sense with regard to implementation programmes, as these are often complex and multifaceted^{28,34} and enabled the second-order analysis.²⁸ The interpretative approach of the realist evaluation²⁵ was considered to be appropriate in evaluating not only why our implementation strategies worked or did not work, but also in which type of context and in which situation. Another strength is that this is the first qualitative study evaluating implementation strategies with regard to SBI, next to numerous qualitative studies on this topic as presented in a review of Johnson et al.²¹

An issue that deserves consideration is the sustainability of the implementation efforts. Future implementation programmes should provide booster training sessions to update knowledge, to set alcohol SBI on the agenda, to maintain SBI skills and institutional support. Also when the professional team formation changes, booster session could be important to reformulate different professional roles within teams. Second, structural payment for preventive services, rather than a temporary project based payment, is important for both short term and for long term. More importantly, implementation strategies on the macro level should be applied to influence the societal and political culture. Only then, initiatives on the micro and meso-level can be highly successful. Successful e-BI strategies deserve further research attention, as the limited e-BI related data in this study impedes to provide full answer on the research questions related to e-BI.

We believe that the present study considerably advanced our understanding of alcohol SBI implementation processes in different contexts. A review of Chaudoir et al. (2013) indicated that organisation, professional and innovation-level constructs have the most usable measures for implementing health innovations, whereas structural and patient-level constructs have the least usable measures.³⁵ Implementing guidelines like alcohol SBI, can be regarded as a ‘health innovation’. When we compare the review results of Chaudoir et al. with the results from the present study, we found that most findings were in agreement with the indicated measures. Factors related to guidelines, individual professionals, incentives and resources as well as a capacity for organisational change were most important in reaching the aim of this study. This study adds the importance of meso- and macro-influences when implementing potentially powerful SBI drivers.

Conclusions

To summarise, T&S essential implementation ingredients seemed to be gained knowledge and skills, team-based training and learning to prioritise SBI during high workloads. FR directed SBI motivations appeared to be highly determined by country context and were influenced by the way reimbursement was provided and by the reimbursing parties. Structural payment is an important precondition. Despite e-BI proved effectiveness in previous lifestyle studies³¹, this study showed that professionals require clear guidance in how the facilitated access can improve SBI in routine practice. To give a complete answer on the e-BI research question of this manuscript, additional research is needed.

These insights gained help to further tailor T&S, FR, and e-BI implementation strategies in order to achieve maximum gains in increasing alcohol SBI and risky alcohol consumption. However, the macro-level in which SBI is augmented to be implemented has an influential role. High potential implementation strategies on the micro level could get nullified due to influences from the macro- level such as societal and political culture. Focusing only on the primary health care setting seems insufficient and a more integrated SBI culture, together with meso- and macro-focused implementation process is requested.

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9

Chapter 9

General discussion

This Ph.D. thesis contributes to the body of knowledge on how to improve alcohol prevention services in primary health care. It provides insight in how to use knowledge of barriers for uptake of screening and brief interventions (SBI) into appropriate implementation strategies for getting SBI embedded in routine primary health care. It also explores why some strategies work, and some strategies don't work or work less well.

Main findings

The potential of a variety of implementation strategies (chapter 2 and 3)

It was hypothesised that a tailored, multi-faceted implementation programme that included combined physician, organisation, and patient directed alcohol-specific implementation strategies, would increase role security and therapeutic commitment in GPs in the Netherlands. The interventions improved GPs' therapeutic commitment significantly but little in absolute terms, and failed to improve GPs' role security in working with risky drinkers. GPs' perceptions of the importance of improving their care for risky alcohol consumption and the reported proportion of patients asked for alcohol consumption at baseline enhanced the effect of the improvement programme on therapeutic commitment. More improvement potential seemed present with regard to SBI uptake by providers. The meta-regression analysis in our systematic review of trials showed that studies with significant effects on SBI outcomes are those that combine patient, professional and organisational oriented implementation strategies. Involving nurses and other health providers were of significant value for improving screening services in primary health care. However, multiple implementation approaches have a stronger impact on ensuring that SBI is delivered than on producing actual reductions in alcohol consumption.

Increasing SBI in primary health care (chapter 4 to 8)

It was expected that the provision of each of training and support, financial reimbursement, and the option of referral to an internet based method of delivering advice (e-BI) would increase SBI proportions and that combining these would be more effective compared to single-focused strategies. This expectation was based on analysis of barriers, each of the strategies was designed to overcome the experienced barriers by primary health care providers. The ODHIN trial showed that combining training and support with financial reimbursement led to higher improvement in primary health care SBI proportions than training and support and financial reimbursement alone. They significantly improved SBI proportions from 8.9 per 1,000 adult patients per practice at baseline, to 24.5 adult patients per practice after implementation. The e-BI referral option, alone or in combination with the other strategies, was not associated with higher SBI proportions.

To explore which factors influence the effect of the ODHIN implementation strategies, we hypothesised that higher baseline role security and therapeutic commitment would result in better implementation of SBI. In addition, we hypothesised that lower age, female providers, practice nurses, health clinics and a lower number of patient population and consultations would be associated with higher implemented brief intervention proportions. These hypotheses were partly confirmed. The type of general practice (solo, duo versus group practice and health centre) and the number of consulting adult patients per provider influenced the effectiveness of financial reimbursement on the brief intervention proportion. As opposed to expected, provider demographic characteristics (such as age and gender) and pre-trial role security and therapeutic commitment had no impact on the implementation of brief interventions. Furthermore, pre-trial role security and therapeutic commitment were not of great importance for baseline alcohol screening and BI proportions.

Subsequent qualitative exploration of *why, how, for whom* and *under what circumstances* the implementation strategies worked or did not work, showed that high SBI proportions seemed to be mainly a result of training and support. It improved, according to the providers, their knowledge and skills and providers also learned to prioritise SBI even when they had a full appointment schedule. They also appreciated the applied team-based approach. Positive SBI intentions remain an important starting point to increase activity. Continuous provision, sufficient time for learning intervention techniques and tailoring to individual experienced barriers, were important perceived conditions for making training and support work. For the Catalan and Polish providers, financial reimbursement seemed an additional stimulating factor as well, while this did not seem to affect provider behaviour in the Netherlands and Sweden. Structural payment for preventive services rather than a temporary project based payment like in ODHIN, would have increased effects of financial reimbursement on the long-run. Implementing e-BI requires more guidance than was delivered in ODHIN. Important preconditions for SBI routine were frequent exposure of this topic in media and guidelines, information systems that facilitate SBI (e.g. screening programmes), and having SBI in protocol-led care. However, the ODHIN study tested implementation strategies at micro-professional level and meso-practice level. The implementation domains that focus on macro-level seemed to exert trialled implementation strategy influences on the meso- and micro level and therefore it raises the need for an approach in which the focus of SBI responsibility is broader than primarily on primary health care.

Discussion of the main findings

That it is not easy to improve SBI performance and role security and therapeutic commitment of primary health care providers, was known from previous studies and is confirmed by the studies reported in this Ph.D. thesis. Despite the efforts made in the

extended tailored and multifaceted improvement programme in the GPA project, which was conducted in 2006 till 2008, it failed to increase role security and only had little (although significant) impact on therapeutic commitment. This lack of effect is consistent with the lack of effect in SBI proportions, that is, the intervention GP group did not show higher SBI proportions compared to the control GP group, who solely received the national guideline.¹ The programme even seemed counterproductive regarding patients' alcohol consumption. The authors recommended future research to patient attitudes, e-learning and a stepped approach in which different strategies are used consecutively instead of simultaneously.² As a lesson from the GPA trial, the ODHIN trial, which was conducted between August 2012 and December 2013, included e-learning and offered single strategies as well as combinations of strategies. This resulted in important insights for improving SBI uptake in primary health care, although effects were rather small (chapter 5) and did not sustain on the long-run.³

In the systematic review in chapter 3, it was recommended for future implementation programmes to combine either professional, patient and organisation oriented implementation programmes to impact on alcohol consumption and SBI proportions in primary health care, and to involve nurses and other health providers besides physicians in implementation strategies. The latter was confirmed in another review, which showed that a nurse-conducted brief intervention is an effective strategy for reducing alcohol consumption.⁴

Although the GPA trial focused on the combination of professional, patient and organisation oriented strategies, this trial did not show increased SBI proportions.¹ One could question what causes this inconsistency with the studies in the systematic review. One explanation might be related to the implementation fidelity of the multifaceted improvement programme. Of the 41 practices that were allocated to the intervention that included educational training sessions, only 20 practices met the minimal demands made on enrolment. Outcomes were analysed with the intention-to-treat principle, meaning that practices and GPs were analysed in the groups to which they were randomly assigned originally, regardless of whether or not they actually participated in the intervention. To meet the minimal demands for enrolment, members of the general practice team had to attend at least one educational session of two to three hours.¹ The impact of the combination of such a low-intensity training session with low implementation fidelity could be questioned, especially with regard to the long term effects.⁵

Another possible explanation is that nursing roles are becoming more and more evident in Dutch health care with over 100 mental health nurses per 100,000 population, of which most are working in primary health care.⁶ So, it might be that focusing GPA implementation strategies not only on GPs but on other mid-level providers such as nurses as well, as was suggested in the systematic review in chapter 3, could have made a difference. Moreover, from the ODHIN qualitative study, it seems

that only training and support had a beneficial effect in the Netherlands, since general practitioners and practice nurses generally reported that they did not feel stimulated by the financial reimbursement provided in the ODHIN study. From the GPA trial we do not know the effects of the singular elements of the intervention group, which leaves a ‘black box’ behind the absence of SBI effects in the end.

Other studies, such as from the World Health Organisation four country (Australia, Belgium, Catalonia and England) collaborative randomised controlled trial, demonstrated the potential of training and support on SBI.⁷ ODHIN gave more insight in interactions of alcohol prevention-focused training and support with other implementation strategies and provided insight in *why, how, for whom* and *under what circumstances* training and support worked. The ODHIN trial showed that those primary health care providers with highest increase in SBI proportions, were present in practices that received training and support combined with financial reimbursement. The increase in SBI through combining these strategies is more than just adding effects of the single strategies. Yet, before stating that every country should offer training combined with financial reimbursement, it seems important to check per primary practice type and per country how to optimally implement SBI. Zooming in on potential factors that inhibit or facilitate the SBI implementation proportions, shows that financial reimbursement had significantly larger effects in solo and duo practices compared with larger practices, and in providers who see relatively high numbers of patients. The qualitative evaluation of ODHIN showed that in countries with cutbacks in personnel and salaries, financial reimbursement additionally stimulates besides training and support.

Moreover, ODHIN measures at six months follow-up (unpublished), showed that the findings shortly after running of the implementation programme did not sustain on the longer term, as only training and support effects partially sustained.³ To make financial reimbursement work in the Dutch context, structural payment for preventive services is required, rather than a temporary project based payment. Those ODHIN primary health care practices that received financial reimbursements during the implementation period did not show improved intervention proportions at six months follow-up, compared to non-reimbursed primary health care practices.³ These findings indicate that permanent investments are required to motivate primary health care providers to perform SBI. This is in line with other health condition areas and risky behaviours that are studied in the context of pay for performance. When implementing lifestyle interventions such as alcohol related screening and brief interventions, it is important to address sustainable funding of services.⁸ Quality of primary health care widely varies between primary health care providers and is influenced by payment systems where payment is based on fee-for-service and capitation systems rather than related to quality of care.⁹ In the United Kingdom (UK), the Quality and Outcomes Framework (QOF) is such a reimbursement scheme. After 20 systematic reviews and one systematic

reviews of systematic reviews¹⁰, it is clear that pay for performance can be effective. However, policy makers should be warned that effects may be only realised on short-term and may be not as large as one may wish.¹⁰ Pay for performance has potential, but it is not a “magic bullet”. To achieve sustainable changes, it needs to be combined with other quality improvement initiations.¹⁰

The third ODHIN implementation strategy, the e-BI referral option, did not influence the alcohol prevention services. Despite the proven effectiveness of SBI self-help via internet^{11,12}, our study confirms the findings of other research showing that primary health care providers hardly use e-health in their patient care.^{13,14} This implies that the tested implementation strategy was not (yet) appropriate for this group of health providers. Although it was communicated as a time-saving strategy, it is likely that professionals should receive more clear guidance in how the facilitated access can really decrease their work pressure by using proved effective e-BI interventions.^{14,15} The Dutch College of General Practitioners believes that the primary health care unit has an important role in the coordinating online communication and information around healthcare.¹⁶ Our study shows that implementation in routine daily practice is still a major challenge.

Methodological reflections

This Ph.D. thesis presents studies that have strengths and weaknesses. Here we focus on some main issues. The ODHIN project did not include measurements of patients' alcohol consumption. In the Netherlands this was attempted, but not succeeded. The research team asked participating general practitioners and practice nurses to hand out questionnaires on those patients they identified as a risky drinker, however very few questionnaires were handed out by providers, mainly due to high workloads as reported by the providers. In the Dutch GPA study patient outcomes were reported, which showed no impact of the implementation strategies.²

The factorial design that was chosen in the ODHIN trial had advantages and disadvantages. Its strength is that it ensured sufficient power to detect small changes with a relatively small number of primary health care practices (i.e. 120).¹⁷ This design allows each condition - i.e. ODHIN implementation strategy - to be separately evaluated compared to the care as usual ODHIN condition.¹⁸ Furthermore, it allows evaluation of combined implementation strategies (synergy), which makes the factorial design more efficient than a four arm parallel trial.¹⁸ In the ODHIN study this means the effect of training and support instead of no training and support can not only be estimated from training and support versus control, but also from training and support+financial reimbursement versus financial reimbursement, training and support+e-BI versus e-BI, and training and support+financial reimbursement+e-BI versus financial reimbursement+e-BI, giving a pooled estimate with more precision. The factorial design is the best appropriate design to detect interactions of interventions.¹⁹

The other side of the coin is that this design is more difficult to understand and needs an expert interpretation of numbers, like in ODHIN an experienced statistician was indispensable with such a design. Another disadvantage, which was not related to the factorial design but to the ODHIN outcome measure, were the highly skewed distributions on outcomes. This required log transformation and lead to more difficulty in interpreting outcomes, as these are relative rather than absolute and, therewith, makes it more complicated to report the results clearly.²⁰

Despite the beneficial effect of training and support combined with financial reimbursement in ODHIN, it should be noted that in fact, there was a drop-off in intervention proportions after baseline in almost all study arms. Yet, primary health care practices that received training and support plus financial reimbursement demonstrated a (280%; 95%-CI 162 to 451) relatively higher intervention proportion than primary health care practices that did not receive training and support plus financial reimbursement. In absolute numbers, all allocation groups dropped in their intervention proportions, of which the training and support plus financial reimbursement group had the least drop. Hence, it could be interpreted that this combination of strategies actually ‘prevented’ primary health care practices from further drop-offs due to high baseline levels. Therefore, these results do not mean that the proportion of patients who received an intervention raised generally from 8.9% at baseline to 24.5% after implementation. It rather means that during the 12 week implementation period the proportions with training and support and financial reimbursement were respectively 280% higher than without training and support and financial reimbursement.

Adequately and objectively measuring SBI outcomes remains a topic for discussion. In the Dutch GPA study data collection was based on reviewing electronic medical records. Dutch medical registration systems are, certainly at the time of conducting the GPA trial, not optimally facilitating in registering preventive services. Therefore it raises the internal validity question: has been measured what was intended to be measured? During ODHIN, participating providers completed tally sheets to report a screening and brief intervention activity. In fact, as the research team was informed afterwards, this can be regarded as an intervention itself as it caused the high baseline SBI levels (Hawthorne effect). There are alternatives, though more intensive measurements possible, such as patient self-report of discussions about alcohol use immediately after the physician visit.²¹ It might be worthwhile to study best methods for monitoring providers SBI proportions, for example in a stepped wedge design. Stepped wedge designs have various types of designs²², though in this context a stepped wedge design with a continuous recruitment short exposure design seems most appropriate. In contrast to stepped wedge trials with closed and open cohorts, carry-over effects do not arise in the continuous recruitment short exposure design²², which

makes it possible to measure without Hawthorne effects. Such a study might be worthwhile not only for alcohol consumption SBI, but other lifestyle themes as well.

Another topic for discussion is the 10-item Shortened Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ). The SAAPPQ is a questionnaire that measures providers' role security and therapeutic commitment in working with patients with alcohol use disorders and comprises five subscales: (a) role adequacy (b) role legitimacy; (c) motivation; (d) task specific self-esteem; and (e) work satisfaction.²³ Given that in ODHIN we have found that the SAAPPQ does not appear predictive (chapter 7 and²⁴) for SBI proportions, the issue of whether or not it is still a useful instrument deserves to be raised and discussed. Subsequently, one could question if the research focus should lie on role security and therapeutic commitment, as these seemed not the major drivers in SBI performance. The SAAPPQ was originally derived from the full AAPPQ²⁵ and criticised by the AAPPQ author before.²⁶ Hence, before banning the SAAPPQ as an inappropriate instrument, it might be worth to measure with the full AAPPQ consisting of 29 instead of 10 statements, to check for similarity in findings compared with SAAPPQ.

A strength and a weakness at the same time is the fact that ODHIN was an international project. The countries that participated in the trial (Sweden, United Kingdom, Poland, Catalonia and the Netherlands) are different in their organisation of primary health care and in their drinking patterns. This creates opportunities to, for instance, build cross-cultural competence and advance health professional practice globally.²⁷ It also created opportunities to identify across country differences, such as the impact of not-having a national guideline on risky alcohol consumption, such as in Poland. Results from this Ph.D. thesis can consequently be applicable through Europe and other similar Western countries. On the other hand, we had to develop implementation strategies that were applicable to all countries and therefore concerned a consensus driven pragmatic strategy. Part of the variability took place at the country level, given the significant intracluster correlation coefficient. Perhaps we would have had greater impact if the strategies were initiatively fitted to country standards. Another strength is combining existing evidence with implementation strategies that were not studied before. For instance, training and support, known as an implementation strategy with proved potential to increase SBI uptake, was combined with financial reimbursement and e-BI, of which effects on SBI uptake were both still unknown in the field of risky alcohol prevention.

A major methodological strength of ODHIN is that quantitative as well as qualitative research methods were conducted. Different perspectives were incorporated to understand the construct of successful SBI implementation.²⁸ Quantitative outcomes informed about which strategies are effective in SBI improvements and to what extent, whereas qualitative outcomes give explanation for these effects on a more in-depth level. Moreover, the qualitative evaluation provided insight in why, how, for whom and

under what circumstances the strategies (would) work in the Netherlands. Such a variety in approaches contributes to the body of implementation research and to the cross-disciplinary dialogue among implementation researchers.²⁹

Improving health care alcohol prevention: the way forward

Implications for primary health care

In the Netherlands, costs of the mental health sector raised substantially compared to other health care sectors such as dental care and paramedical care, and also compared to all other countries except the United States. Most mental health treatments are conducted in the primary health care setting.³⁰ Therefore, strengthening primary health care capacities for adequate SBI implementation is requested. To prevent expensive secondary care costs, Dutch primary health care was strengthened last decennia by integrating primary health care psychologists and mental health practice nurses in the Dutch primary practice. However, secondary care costs did not decrease and it seems that collaboration between the traditional primary health care team and additional professional mainly led to improved registration of referrals and not to substitution of care. So, despite presence of additional primary health care disciplines, the 'traditional primary health care team' consisting of GP and nurse, remains an important provider of mental health care including alcohol SBI.³¹

Another starting point to increase the SBI services uptake in primary health care, might be to strengthen the connection between patient (unspoken) demands and primary health care offered services. Compared to other western European countries, Dutch GP's indicate to know their patients less well than GPs in other countries.³² In addition, in 14% of the cases, Dutch GP's made a psycho-social diagnosis (including addictions) in the absence of a related request from the patient. This is significantly less frequent compared to other countries with GPs in a strong primary care system.³² It is important to conduct further research on this, as Prins et al (2014) showed that after psychological treatment, patients contact their GPs less often and present fewer psychological or social problems.³³ Yet, the study of Sinnema et al (2015) showed that those GPs who received a tailored implementation programme, improved in recognition and consultations addressing anxiety and depression, but that this improvement did not affect patient symptom reduction or improvement of functional status. In addition, there are concerns about the costs of the implementation programme. The authors recommend further research for guideline implementation before large-scale implementation can be recommended.³⁴

It is not the workload of Dutch GP's that affects their awareness of patients' psychological problems, except for the finding that a GP with an experienced lack of time is less patient-centred. Zantinge et al (2007) additionally recommend to give special attention to communication skills required to discuss psychological problems such as risky alcohol consumption.³⁵ This may be an important confirmation of our

finding that the ODHIN training and support that was primarily focused on communication skills, even in short duration, is effective for improving alcohol SBI.

Implications for prevention beyond primary health care: community health care

Alcohol has been part of human culture for thousands of years.³⁶ Primary health care providers are part of this culture - almost 90% of the Dutch GPs consume alcohol.³⁷ In such a culture where it is commonly perceived as normal to consume alcohol, one might imagine that a focus on primary health care to decrease population's alcohol consumption is not sufficient. In previous decades, there has been increasing attention for the harmfulness of alcohol. For instance, some non-primary health care related changes were introduced in the Netherlands, such as an increase of the legal drinking age from 16 years to 18 years. Monitoring and surveillance of this introduced law has been conducted. There are several strong policy measures available, the introduction of preventive interventions is just one of those. Policy covering availability, marketing, pricing, drink-driving policies are proved to be very effective in reducing drinking.³⁸ The primary health care providers who participated in the ODHIN qualitative study, are convinced that when surrounding policies have more attention for risky alcohol prevention, they also are more aware of risky alcohol consumption in their own routine care. In Dutch general practice the awareness of healthy lifestyles increases of the last years.³⁹ Discussions about smoking behaviour and physical activity increased over time, however changes in nutrition and alcohol consumption discussions are less clear. Alcohol is the least discussed lifestyle theme of these four.³⁹

Besides these public health interventions, the scientific base that compares beneficial effects of alcohol with harmful effects of alcohol consumption shows more and more that the harmful effects are stronger than beneficial effects, leading to the conclusion that there are no protective effects of alcohol in gender and age groups, despite in a small subgroup of women aged 65 years or more and with just a small amount of alcohol.⁴⁰ The authors warn that this protective association may be explained by the effect of selection bias.⁴⁰ Dutch elderly increasingly consume alcohol and exceed the level of consumption that might have a protective effect on health.⁴¹ Although the Dutch population is ageing, the ageing of clients in addiction care is developing more rapidly than in the general population, caused by alcohol related treatment and opiates related treatment.⁴¹ These developments raise the need for action, which has to be taken up broader than only by primary health care. The Dutch government started in 2007 various initiatives to transfer care from secondary to primary and community health care and started the programme 'Home Care Prevention force' (in Dutch: Preventiekracht Thuiszorg). This nationwide programme was aimed to strengthen prevention in community health care and is, amongst others, focused on cost-effective prevention and health promotion, and on strengthening collaboration between local stakeholders.⁴² Yet, this is a generally unexplored area in the scientific

field of health research and more knowledge on how to effectively involve community health care in alcohol prevention is required.

A study of van de Glind et al (2015) indicated that whether lifestyle interventions are well evaluated or not, does not seem relevant for the degree of uptake in daily practice.⁸ A qualitative study in Dutch GPs and practice nurses showed that most cited facilitators of having lifestyle discussions with their patients, are availability of a practice nurse, collaboration with other disciplines and availability of interventions in their own practice.⁴³ ODHIN addressed the first and third mentioned facilitator, but was not able to address collaboration with other disciplines. Although the ODHIN trial results may indicate there is potential for improvement in alcohol prevention services, it is also clear that work load in primary health care is high. Therefore, the focus should go beyond primary health care, which remains a very important link in the chain of risky alcohol prevention activities, but primary health care cannot do it alone. As treatment of mental health disorders had been shifted the last decade more and more towards primary health care, this is also true for alcohol related disorders. There seems to be a shift towards more integrated mental health care.⁴⁴ This may also be true for alcohol prevention as part of mental health prevention. That is, mental health preventive services should be integrated in more settings at the same time to create a synergetic effect. As Room et al (2015) say, if we would like to change cultures in which drinking is part of the culture, we must take account of the collective nature of drinking and of the interplay of influences.⁴⁵ Such a collective nature of prevention could be imagined by integrating prevention by at least primary health care, community health care and mental home health care.

Recommendations for future research

This Ph.D. thesis induces several themes that could be the focus of future research. For instance, the effect of SBI on alcohol consumption seems reasonably clear⁴⁶⁻⁴⁸, although effects of implementation strategies focused on providers' SBI uptake on patient alcohol consumption with attention for fidelity, remain unclear. Also financial reimbursement in collaboration with health insurances to test the strategy in another, less project-based and more fundamentally health insurance based context, are required. Furthermore, there should be attention for facilitating medical record systems that facilitate monitoring of registering preventive activities.^{49,50} The ODHIN participants reported it as an important condition for changing daily practice. But what's the most important driver for future research, is to gain knowledge about how to stimulate SBI uptake with a more integrated approach, in which other health care setting play a role as well. The results of this Ph.D. thesis indicate a twin-track research procedure.

First, many GPs indicate they are willing to provide brief interventions and counselling, and they are also open to learn and improve skills. However, they do not

feel powered and do not see rationale for structural screening for alcohol-related problems. Therefore it seems reasonable to distinct between screening recommendations and brief intervention recommendations. With regard to screening, a selective screening procedure seems to fit best in GPs' daily practice. In the selective screening procedure the GP recognises direct as well as indirect signals of risky drinking. This is in line with the current and revised primary health care guideline in the Netherlands.⁵¹ However, the relatively low baseline screening proportions in ODHIN as well as reactions on offered training and support indicate that many GPs can improve their knowledge about direct and indirect signals of risky drinking in their patients. Subsequently, the practice nurse has an important role in disease prevention and health promotion in primary health care and works according to protocols. Therefore, in contrast, the practice nurse can apply opportunistic screening with patients, which is something that most nurses already do and should maintain.

Second, researchers and policy makers should shift their focus somewhat from the primary health care practice to other potential settings for implementation of interventions. In ODHIN, 5.9% of all patients that could have been screened by primary health care providers, were actually asked for their alcohol consumption at baseline. Training and support combined with financial reimbursement caused a relative difference of 186% in screening proportion, in favour of the providers that received the combined strategy. This is obviously an important improvement, although there still are many patients not screened, who could benefit screening and advice in primary health care settings. Given the low enrolment rate of ODHIN trial participants (i.e. around 7% in the Netherlands), it is likely that these providers had a relatively high motivation compared to the general primary health care provider population. This means that the results of the trial could be less positive for the general primary health care provider population and raises the need for additional resources in different public and health care settings to take up risky alcohol prevention and take part of the screening job. Primary health care needs to be partnered by another setting that, likewise as primary health care, reaches many people. Such a setting is community health care. As there are many shifts from hospital and primary health care to community health care⁵², community health care professionals, i.e. district nurses seem suitable to take over part over the screening job. Future research can inventory the appropriate procedure of screening and brief intervention agreements between district nurse, practice nurse and GP. Furthermore, in the Netherlands the Bachelor of Nursing 2020 project describes future curriculum profiles for nurses in training from year 2020. As such, prevention and self-management are increasingly important in nurses' competencies⁵³ and it would be worthwhile to research how GP, practice nurse and district nurse can collaborate to integrate prevention of risky alcohol consumption in the care for their local geographical area when educated by the BN2020 profile. This is a relatively new area of integrated care in the research field and seems to have high potential.

Final conclusion

This Ph.D. thesis showed how to improve alcohol prevention services in primary health care, although effects were limited. Training and support combined with financial reimbursement are drivers for SBI uptake, although effectiveness of financial reimbursement depends on country context. Undeterred by several future research areas to in-depth identify important nuances within effective primary health care implementation strategies, this Ph.D. thesis showed that preventive power of primary health care is important, but limited. Great investments result in relatively little results that barely lasts on the long term. This requires substantial additional and facilitating impulses on which primary health care can build on. Risky alcohol prevention should be embedded in an integrated and collaborative health care context, in which the role of community health care providers in alcohol prevention and alcohol-induced effects together with primary health care is an interesting area to be explored.

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Summary

Alcohol consumption per capita in Europe is higher than anywhere else in the world. Almost 15% of the world's population aged 15+ live in the World Health Organization (WHO) European Region, but consume a quarter of the total alcohol consumed worldwide (i.e. 23.7 grams of pure alcohol per day). In the European Union (EU) 1 in every 7 deaths in men and 1 in every 13 deaths in women in the group aged 15-64 years was related to alcohol consumption. It contributes to more than 200 diseases, injuries and other health conditions with ICD-10 codes. Evidence shows that 20-30% of patients who present in primary healthcare are risky drinkers. Meta-analyses have shown that simple screening consisting of a few standardised questions, followed by a brief counselling intervention (consisting of simple advice or psychological counselling) significantly reduces alcohol consumption in primary healthcare populations. However, in current primary health care practice less than 10% of the population at risk are identified, and less than 5% of those who could benefit are offered screening and brief advice. Therefore, the overall aim of this thesis was to evaluate how to implement screening and brief interventions (SBI) for risky alcohol consumption in the primary health care setting and to evaluate the impact of providers' role perception and therapeutic commitment in managing patients with risky alcohol consumption.

The content of this Ph.D. thesis is largely based on the studies conducted within the European ODHIN project (Optimizing Delivery of Healthcare Interventions), which focused specifically on the implementation of screening and brief intervention in primary health care and the role of providers' role security and therapeutic commitment in this process.

Potential of a variety of implementation strategies

In **chapter 2** the effect of a tailored multi-faceted implementation programme was evaluated on Dutch GPs' increase in role security and therapeutic commitment. In a cluster randomised controlled trial, 124 GPs from 82 Dutch general practices were randomised to either the intervention or control group. The tailored, multi-faceted intervention included combined physician (e.g. educational sessions), organisation (e.g. facilitating cooperation with local addiction services), and patient directed (e.g. patient information letters and waiting room posters) alcohol SBI implementation strategies. The control group was mailed the national guideline and patients received feedback letters. Questionnaires were completed before and 12 months after start of the programme. We performed linear multilevel regression analysis to evaluate effects of the implementation programme. The interventions improved GPs' therapeutic commitment significantly but little in absolute terms, and failed to improve GPs' role security in working with risky drinkers. GPs' perceptions of the importance of improving their care for risky alcohol consumption, and the reported proportion of patients asked

for alcohol consumption at baseline, enhanced the effect of the improvement programme on therapeutic commitment though the effect retained small.

Chapter 3 describes a meta-analysis of 29 SBI implementation trials. Key outcomes included alcohol consumption, screening, brief interventions and costs in primary health care. Standardised mean differences were calculated to indicate the impact of implementation strategies on key outcomes. Effect sizes were aggregated using meta-regression models. Studies with significant effects on SBI outcomes are those that combine patient, professional and organisational oriented implementation strategies. Involving nurses and other health providers next to physicians were of significant value for improving screening services in primary health care. However, multiple implementation approaches have a stronger impact on ensuring that SBI is delivered than on producing actual reductions in alcohol consumption.

Increasing SBI in primary health care

In chapter 4 to 8 the ODHIN trial is reported. **Chapter 4** presents a study protocol of a cluster randomised factorial controlled trial. In Sweden, Catalonia, Poland, England and the Netherlands the impact of training and support, financial reimbursement, and referral to an internet-based method of delivering advice (e-BI), singly or in combination, was measured on primary health care providers' intervention proportions for risky drinkers. 120 primary health care units, evenly distributed throughout the five countries, were randomly allocated to one of eight groups: care as usual, training and support, financial reimbursement, e-BI, paired combinations out of the three strategies, and all of the three implementation strategies.

Chapter 5 describes the relation between existing levels of alcohol screening and brief intervention proportions, and role security and therapeutic commitment by the participating primary healthcare professionals. Results were derived from baseline measurements of the trial as described in chapter 4. The findings show that both role security and therapeutic commitment are not of great importance for actual alcohol screening and BI proportions.

In **chapter 6** results of the trial were presented from a multilevel analysis with linear model. The participating 120 primary health care units included 746 primary health care providers. Combining training and support with financial reimbursement led to highest relative improvement in primary health care SBI proportions and higher than training and support and financial reimbursement alone. They significantly improved SBI proportions from 8.9 per 1,000 adult patients per practice at baseline, to 24.5 adult patients per practice after implementation. The e-BI referral option, alone or in combination with the other strategies, was not associated with a higher SBI proportion.

To explore which factors influenced the ODHIN implementation process, **chapter 7** presents analyses of impact from demographics as age, gender, occupation; pre-trial role security and therapeutic commitment; and working conditions as primary health care unit type, number of primary health care unit registered patients, and number of consulting adult patients per provider. Results revealed that the effectiveness of financial reimbursement on the brief intervention proportion were only influenced by the type of general practice (solo, duo versus group practice and health centre) and the number of consulting adult patients per provider. Financial reimbursement effects were relatively higher with solo and duo practices, and with providers that had relatively high patient consultations. The implementation process was not influenced by demographic characteristics (such as age and gender) or pre-trial role security and therapeutic commitment.

A qualitative evaluation of the trial was presented in **chapter 8**. This qualitative study aimed to provide more insight into the factors and mechanisms of why, how, for whom and under what circumstances implementation strategies work or do not work in increasing SBI. Semi-structured interviews were conducted with 68 GPs and nurses in Catalonia, the Netherlands, Poland, and Sweden. Realist evaluation was combined with the TICD framework for identification of implementation determinants to guide the interviews and analysis. Participating providers represented 38 providers with a high screening performance and 30 with a low screening performance. Training and support motivated SBI by improved knowledge and skills and it taught professionals to prioritise SBI team-wise, even during high workload. Positive SBI intentions remain an important starting point for increasing activities. Continuous provision, sufficient time to learn intervention techniques and to tailor to individual experienced barriers, seemed important conditions to make training and support work. Catalan and Polish professionals perceived financial reimbursement to be an additional stimulating factor as well, as effects on SBI were smoothened by personnel levels and salary levels. Structural payment for preventive services rather than a temporary project based payment like in ODHIN, might have increased the effects of financial reimbursement. Implementing e-BI seem to require more guidance than was delivered in ODHIN. Despite the allocation, important preconditions for SBI routine seemed frequent exposure of this topic in media and guidelines, SBI facilitating information systems, and having SBI in protocol-led care. Hence, the second order analysis revealed that the applied implementation strategies have high potential on the micro and meso-level, however due to influences from the macro- level such as societal and political culture the effects risks to get nullified and therefore should be emphasised.

Finally, the main findings of this Ph.D. thesis are discussed in **chapter 9** in the light of recent literature. Implications for future research, preventive clinical practice and policy makers are outlined. This Ph.D. thesis showed how to improve alcohol prevention services in primary health care, although effects were limited. Training and support combined with financial reimbursement are drivers for SBI uptake, although effectiveness of financial reimbursement depends on country context. Undeterred by several future research areas to in-depth identify important nuances within effective primary health care implementation strategies, this Ph.D. thesis showed that preventive power of primary health care is important but limited. Large investments result in relatively little impact that barely lasts on the long term. This requires additional facilitating impulses and collaborations creating synergy in taking up risky alcohol prevention. Risky alcohol prevention should be embedded in an integrated and collaborative health care context, in which the role of community health care providers in alcohol prevention and alcohol-induced effects together with primary health care is a promising area to be explored.

Samenvatting

Wereldwijd heeft Europa de hoogste alcohol consumptie per hoofd van de bevolking. Hoewel ongeveer 15% van de wereldbevolking vanaf vijftien jaar in Europa woont (volgens indeling van de Wereldgezondheidsorganisatie standaard), wordt een kwart van de wereldwijde alcoholconsumptie in Europa geconsumeerd. Dit komt overeen met 23,7 gram pure alcohol per dag. In de Europese Unie is bij 1 op de 7 overleden mannen en bij 1 op de 13 overleden vrouwen in de leeftijdsgroep 15-64 jaar het overlijden gerelateerd aan alcohol. Alcohol consumptie draagt bij aan meer dan 200 ziekten, letsels en andere aandoeningen volgens de ICD-10 indeling. Studies tonen aan dat 20-30% van de patiënten in de eerstelijns overmatig drinken. Meta-analyses laten zien dat screening bestaande uit enkel een paar standaard vragen, gevolgd door een korte begeleiding (bestaande uit een kort advies of psychologische begeleiding) de alcohol consumptie al significant vermindert. Toch wordt in de huidige eerstelijns minder dan 10% van de risicopopulatie herkend en minder dan 5% van de patiënten die er voordeel bij zouden kunnen hebben, ook daadwerkelijk screening en kort advies aangeboden. In dit proefschrift onderzochten we hoe screening en kortdurende interventies tegen overmatig alcoholgebruik geïmplementeerd kunnen worden in de eerstelijns. Hierbij onderzochten we tevens de impact van rolperceptie en therapeutische betrokkenheid van zorgverleners ten opzichte van het werken met overmatige drinkers.

Dit proefschrift bevat voornamelijk resultaten uit de Europese ODHIN studie (Optimizing Delivery of Healthcare Interventions). Dit project richtte zich specifiek op de implementatie van screening en kortdurende interventies in de eerstelijns en op de rol van rolperceptie en therapeutische betrokkenheid van zorgverleners in dit proces.

Potentie van verschillende implementatiestrategieën

In **hoofdstuk 2** wordt gekeken in hoeverre een op maat implementatieprogramma met meerdere implementatiestrategieën invloed heeft op de rolperceptie en therapeutische betrokkenheid van Nederlandse huisartsen ten opzichte van het werken met overmatige drinkers. In een cluster gerandomiseerde gecontroleerde studie werden 124 huisartsen afkomstig uit 82 huisartsenpraktijken gerandomiseerd naar een interventie of controle groep. Het op maat implementatieprogramma behelsde implementatiestrategieën die gericht waren op zowel de arts (bijvoorbeeld scholing), organisatie (bijvoorbeeld faciliteren samenwerking met verslavingszorg) als patiënt (bijvoorbeeld patiëntinformatiebrieven en wachtkamerposters). De controlegroep van zorgverleners ontving de nationale richtlijn en patiënten ontvingen brieven met terugkoppeling op hun alcohol consumptie. De zorgverleners vulden vragenlijsten in voorafgaand aan en twaalf maanden na start van het programma. We voerden lineaire multilevel regressie analyse uit om effecten van het implementatieprogramma op de rolperceptie en therapeutische betrokkenheid van de huisartsen te meten. Het programma verbeterde de therapeutische betrokkenheid van de huisarts significant maar in geringe mate en

had geen effect op de rolzekerheid van de huisarts in het werken met overmatige drinkers. Het belang dat huisartsen hechten aan zorgverbetering voor overmatige drinkers én het aantal patiënten dat zij bevragen naar hun alcoholconsumptie vergrootte het effect van het programma op de therapeutische betrokkenheid, doch bleef het effect gering.

Hoofdstuk 3 beschrijft een meta-analyse van screening en kortdurende interventie implementatie studies. Uitkomstmaten waren alcohol consumptie, screening, kortdurende interventies en kosten in de eerstelijns. Gestandaardiseerde gemiddelde verschillen werden berekend om te kijken of de implementatiestrategieën effect hadden op een van de uitkomstmaten. Effectmaten werden berekend met behulp van meta-regressie modellen. De studies met significante resultaten op screening en kortdurende interventies combineren strategieën die op patiënt, zorgverlener en organisatie gericht zijn. Het betrekken van verpleegkundigen en andere zorgverleners naast artsen was van significante toegevoegde waarde in het screenen van eerstelijnspatiënten. Echter, deze combinatie van strategieën heeft een groter effect op de aangeboden zorg van screening en kortdurende interventies, dan op het daadwerkelijk verlagen van de alcohol consumptie.

Verhogen van screening en kortdurende interventies in de eerstelijns

Hoofdstukken 4 tot en met 8 presenteren resultaten uit de ODHIN trial. **Hoofdstuk 4** presenteert een studieprotocol van een cluster gerandomiseerde factoriële gecontroleerde studie in Zweden, Catalonië, Polen, Engeland en Nederland. We keken hierbij naar de impact van training en ondersteuning, financiële vergoedingen en ondersteuning bij doorverwijzing naar e-health, enkel of in combinatie aangeboden, op de frequentie van aangeboden interventies voor overmatige drinkers. 120 huisartsenpraktijken gelijk verdeeld over de vijf landen werden willekeurig toegewezen aan een van de acht groepen: standaard zorg, training en ondersteuning, financiële vergoedingen, e-health, gepaarde combinaties en alle drie de implementatiestrategieën.

Hoofdstuk 5 beschrijft de relatie tussen alcohol screening en kortdurende interventies enerzijds en rolzekerheid en therapeutische betrokkenheid bij deelnemende eerstelijns zorgverleners anderzijds. De resultaten waren afkomstig van de voormeting van de ODHIN trial. Zowel rolzekerheid als therapeutische betrokkenheid blijken nauwelijks van belang op de frequentie van uitgevoerde screening en kortdurende interventies.

In **hoofdstuk 6** worden de resultaten van de studie gepresenteerd met behulp van multilevel analyses met lineair statistisch model. In de 120 huisartsenpraktijken namen 746 zorgverleners deel aan de studie. Het combineren van training en ondersteuning

met financiële vergoedingen bleek tot de grootste verbetering van screening en kort adviesfrequentie te leiden, groter dan enkel training en ondersteuning of enkel financiële vergoedingen. Ze vergrootten de frequentie van gemiddeld 8,9 per 1000 volwassen patiënten per praktijk bij de voormeting, naar 24,5 volwassen patiënten per praktijk na implementatie. De e-health verwijs optie, enkel of in combinatie met de overige strategieën, leidde niet tot een hogere screening en korte interventie frequentie.

Om te bepalen welke factoren het ODHIN implementatieproces beïnvloedden, presenteert **hoofdstuk 7** een analyse van de impact van demografische variabelen zoals leeftijd, geslacht, beroep; rolzekerheid en therapeutische betrokkenheid bij aanvang van de studie; en werkcondities zoals het type huisartsenpraktijk, aantal geregistreerde patiënten in de praktijk en het aantal patiëntconsulten per zorgverlener. De resultaten lieten zien dat de effectiviteit van financiële vergoedingen verschilde per type praktijk (dat wil zeggen solo- of duopraktijk versus groepspraktijk of gezondheidscentrum) en het aantal patiëntconsulten per zorgverlener. Effecten van financiële vergoeding waren relatief groter bij solo- en duopraktijken, en bij zorgverleners die relatief veel patiëntconsulten hebben. De demografische kenmerken van de zorgverlener, alsook de rolzekerheid en therapeutische betrokkenheid bij aanvang van de studie hadden geen invloed op het implementatieproces.

Een kwalitatieve evaluatie van de studie wordt weergegeven in **hoofdstuk 8**. Het doel van deze studie was om inzicht te krijgen in de factoren en mechanismen in het waarom, hoe, voor wie en onder welke omstandigheden de implementatiestrategieën werkten bij het verhogen van de screenings- en korte interventiefrequentie. Er zijn semigestructureerde interviews gehouden met 68 huisartsen en verpleegkundigen uit Catalonië, Nederland, Polen en Zweden. De interviews en analyses werden gestuurd vanuit de Realist Evaluation gecombineerd met het TICD raamwerk voor identificatie van implementatie determinanten. Er namen 38 zorgverleners deel met een hoge screeningsfrequentie en 30 met een lage screeningsfrequentie. Training en ondersteuning motiveerde screening en kortdurende interventies middels kennis en vaardigheden. Het leerde de zorgverleners ook om prioriteit te geven aan screening en kortdurende interventies, zelfs onder hoge werkdruk. Positieve houding ten opzichte van screening en kortdurende interventie intenties blijken echter wel een belangrijk startpunt voor verdere verbetering. Continue training, voldoende tijd om interventietechnieken aan te leren en kennis te kunnen toepassen op de eigen werksituatie bleken belangrijke voorwaarden om training en ondersteuning te laten werken. Daarnaast werken de financiële vergoedingen volgens de Catalaanse en Poolse zorgverleners stimulerend, maar hierin verschilden zij van visie in vergelijking met hun Zweedse en Nederlandse collega's. Personeelsbezetting en salaris zijn hierbij

bepalende factoren. Het effect van financiële vergoedingen zou kunnen worden verhoogd wanneer deze structureel worden aangeboden voor preventieve zorgverlening, in plaats van betaling op projectbasis (tijdelijk) zoals in ODHIN. Verder lijkt het implementeren van e-health meer begeleiding te vragen dan werd aangeboden in ODHIN. Daarnaast waren er voorwaarden die los staan van de allocatie. Frequent aandacht voor dit thema in de media, informatiesystemen die preventieve zorgverlening zoals screening en kortdurende interventies faciliteren en het toepassen van geprotocolleerde screening en kortdurende interventiezorg zijn de belangrijkste randvoorwaarden hierin. Echter, de tweede-orde analyse van hoofdstuk 7 liet zien dat de implementatiestrategieën dan wel hoge potentie op micro- en meso-niveau zoals zorgverlener en huisartsenpraktijk hebben, maar de invloeden vanuit het macroniveau zoals maatschappelijke en politieke cultuurinvloeden kunnen de bereikte effecten teniet doen en moeten daarom benadrukt worden.

Tenslotte worden de belangrijkste bevindingen van dit proefschrift in **hoofdstuk 9** besproken in het licht van de recente literatuur en zijn de implicaties voor toekomstig onderzoek, de preventieve klinische praktijk en beleidsmakers bediscussieerd. Dit proefschrift laat zien hoe preventieve zorgverlening in de huisartsenpraktijk ten aanzien van overmatig alcoholgebruik kan worden verhoogd, desalniettemin waren de effecten beperkt. Training en ondersteuning gecombineerd met financiële vergoedingen zijn bevorderaars van screening en kortdurende interventiezorg, waarbij het effect van de financiële vergoedingen afhangt van de landcontext. Er zijn verschillende kansen voor vervolgonderzoek benoemd in de huisartsenpraktijk ter nuancering van het implementatieproces, echter we concluderen ook dat de potentie van screening en kortdurende interventiezorg in de huisartsenpraktijk belangrijk maar beperkt is. Grote investeringen resulteren in relatief geringe effecten die nauwelijks beklijven op de langere termijn. Dit vraagt om substantieel aanvullende impulsen waar de huisartsenpraktijk op kan bouwen. Preventie van overmatig alcoholgebruik zou moeten worden ingebed in een geïntegreerde gezondheidszorg die geënt is op samenwerking. Het verdient aandacht om te kijken naar wat de samenwerking tussen de huisartsenpraktijk met andere zorgverleners in de wijk kan opleveren voor alcoholpreventie en hoe dit uiteindelijk de schadelijke effecten als gevolg van alcohol verder kan inperken.



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Curriculum Vitae

Myrna Keurhorst is op 8 september 1988 geboren in het Gelderse Twello. In 2006 behaalde zij haar Atheneum diploma aan het Veluws College in Apeldoorn waarna zij met de studie Gezondheids- & Levenswetenschappen aan de Vrije Universiteit in Amsterdam startte. Haar Bachelor sloot ze af met onderzoek naar prevalentie en preventie van postpartum depressies. Hierna behaalde Myrna de Master Gezondheidswetenschappen met specialisatie Preventie en Volksgezondheid en deed hierbij onderzoek naar preventie van symptoomverergering van ADHD bij jongvolwassenen bij GGNet in Warnsveld.

In 2011 startte ze bij het Scientific Institute for Quality of Healthcare (IQ healthcare) van het Radboudumc in Nijmegen met haar promotiestudie naar implementatie van alcoholpreventie in de huisartsenpraktijk. De resultaten van deze studie zijn beschreven in dit proefschrift. In het eerste promotiejaar combineerde ze dit met een onderzoek naar het gewenste competentieprofiel van de toekomstige wijkverpleegkundige, in opdracht van de Hogeschool van Arnhem en Nijmegen (HAN). Daarnaast voerde Myrna onderzoek uit voor het Partnership Vroegsignalering Alcohol (PVA). Ze schreef hiervoor diverse rapporten en regisseerde lokale pilots ter evaluatie en implementatie van alcoholpreventie bij ouderen in de eerstelijns. Hiermee is ze in 2014 uitgeroepen tot 'Alcoholgoeroe 2014' bij het slotcongres Partnership Vroegsignalering Alcohol en was ze medeprijswinnaar 'Stichting SAB Prijs 2014 in het kader van alcohol en ouderen' met het project 'Alcohol mij 'n zorg'. Medio 2014 tot maart 2015 was Myrna tevens gastdocent wetenschapsonderwijs bij de HAN opleiding Physician Assistant.

Sinds maart 2015 werkt Myrna als docent-onderzoeker geriatrische en palliatieve zorg bij het lectoraat Verpleegkunde en de opleiding HBO-verpleegkunde bij Saxion. Ze verricht hierbij praktijkgericht onderzoek naar en doceert over kwaliteit van geriatrische en palliatieve zorg en houdt zich bezig met onderzoeksonderwijs. Ze is verloofd met Rinus Pelgrum en samen wonen zij in Zutphen.

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